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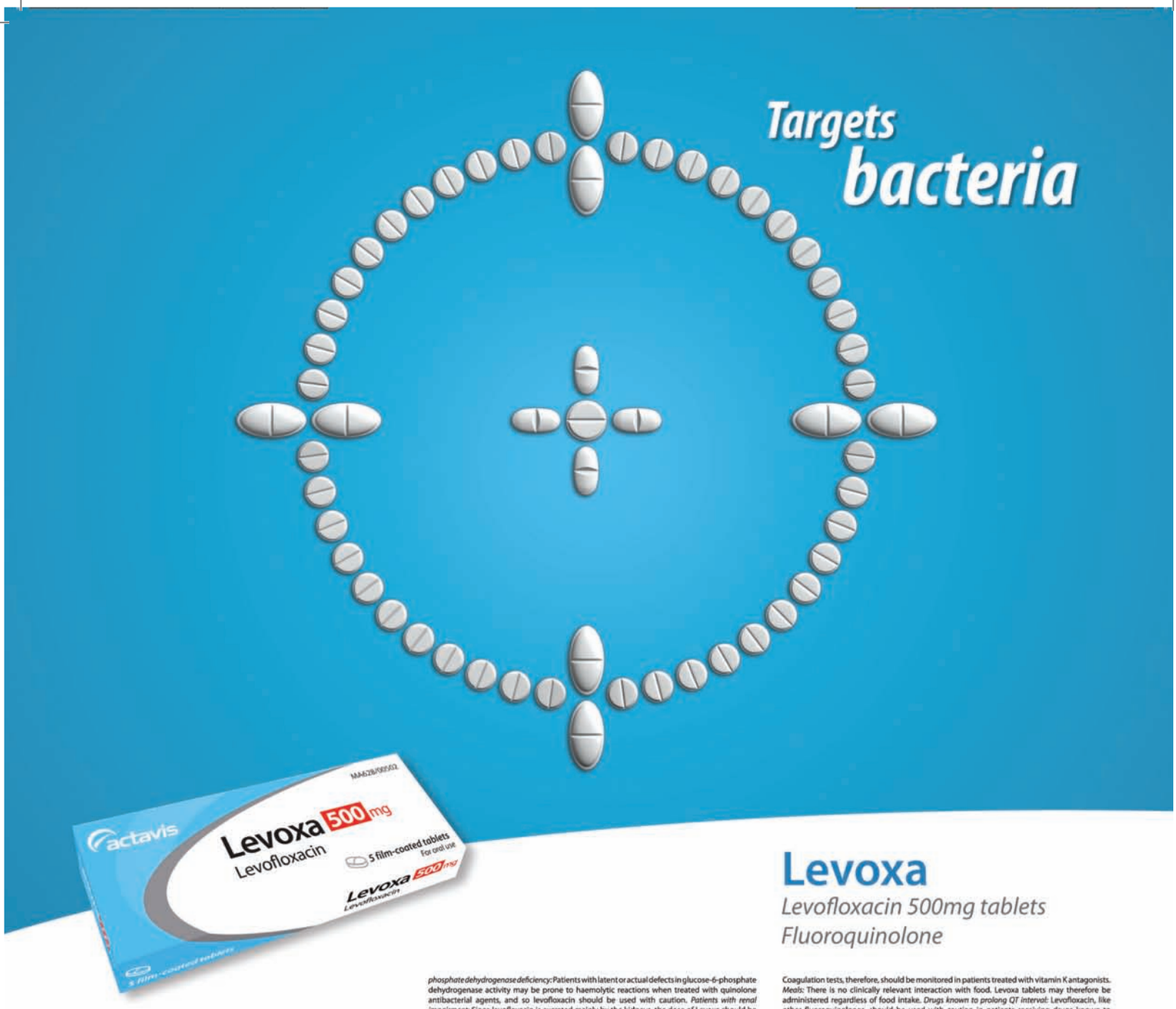

Levoxa

Levofloxacin 500mg tablets
Fluoroquinolone

Composition: Levofloxacin 500 mg film coated tablets. **Therapeutic indications:** In adults with infections of mild or moderate severity, Levoxa tablets are indicated for the treatment of the following infections when due to levofloxacin-susceptible microorganisms: Acute sinusitis, Acute exacerbations of chronic bronchitis, Community-acquired pneumonia, Urinary tract infections including pyelonephritis, Chronic bacterial prostatitis and Skin and soft tissue infections. Before prescribing Levoxa, consideration should be given to national and/or local guidance on the appropriate use of fluoroquinolone. **Posology and method of administration:** *Duration of treatment* - varies according to the course of the disease. As with antibiotic therapy in general, administration of Levoxa tablets should be continued for a minimum of 48 to 72 hours after the patient has become afebrile or evidence of bacterial eradication has been obtained. *Method of administration* - Levoxa tablets should be swallowed without crushing and with sufficient amount of liquid. They may be divided at the score line to adapt the dosage. The tablets may be taken during meals or between meals. Levoxa tablets should be taken at least two hours before or after iron salts, antacids and sucralfate administration since reduction of absorption can occur. The following dose recommendations can be given for Levoxa: *Dosage in patients with normal renal function (creatinine clearance > 50 ml/min)* - Acute sinusitis: 500mg once daily; 10-14 days, Acute exacerbations of chronic bronchitis: 250-500mg once daily; 7-10 days, Community-acquired pneumonia: 500mg once or twice daily; 7-14 days, Uncomplicated urinary tract infections: 250mg once daily; 3 days, Complicated urinary tract infections including pyelonephritis: 250mg once daily; 7-10 days, Chronic bacterial prostatis: 500mg once daily; 28 days, Skin and soft tissue infections: 250mg once daily or 500mg once/ twice daily for 7-14 days. *Dosage in patients with impaired renal function (creatinine clearance 50ml/min):* 50-20 ml/min: First dose 250mg/24h, then 125mg/24h, First dose 500mg/24h, then 250mg/ 24h, First dose 500mg/12h, then 250mg/ 12h; 19-10 ml/min: First dose 250mg/24h, then 125mg/48h, First dose 500mg/24h, then 125mg/ 24h, First dose 500mg/12h, then 125mg/ 12h; <10 ml/min (including haemodialysis and CAPD): First dose 250mg/24h, then 125mg/48h, First dose 500mg/24h, then 125mg/ 24h, First dose 500mg/12h, then 125mg/ 24h. *Patients with impaired liver function:* have not been examined in clinical studies. However, no adjustment of dosage is expected to be necessary, since levofloxacin is not metabolised to any great extent by the liver and is mainly excreted by the kidneys. *Elderly patients:* No adjustment of dosage is required in the elderly, other than that imposed by consideration of renal function. **Contraindications:** hypersensitivity to levofloxacin or other quinolones or any of the excipients, epilepsy, history of tendon disorders related to fluoroquinolone administration, children or growing adolescents, pregnancy and breast-feeding women. **Special warnings and precautions for use:** Levoxa is not always the optimal therapy in pneumococcal pneumonia, particularly in more severe cases. Nosocomial infections due to *Pseudomonas aeruginosa* may require combination therapy. *Tendinitis and tendon rupture:* Tendinitis may rarely occur. It most frequently involves the Achilles tendon and may lead to tendon rupture. The risk of tendinitis and tendon rupture is increased in the elderly and in patients using corticosteroids. Close monitoring of these patients is therefore necessary if they are prescribed Levoxa. All patients should consult their physician immediately if they experience symptoms of tendinitis. If tendinitis is suspected, treatment with Levoxa must be stopped immediately, and appropriate treatment (e.g. immobilisation) must be initiated for the affected tendon. *Clostridium difficile-associated disease:* Diarrhoea, particularly if severe, persistent and/ or bloody, during or after treatment with Levoxa tablets, may be symptomatic of *Clostridium difficile*-associated disease, the most severe form of which is pseudomembranous colitis. If pseudomembranous colitis is suspected, Levoxa tablets must be stopped immediately and patients should be treated with supportive measures and specific therapy as appropriate without delay (e.g. oral vancomycin). Products inhibiting the peristalsis are contraindicated in this clinical situation. *Patients predisposed to seizures:* Levoxa tablets are contraindicated in patients with a history of epilepsy and, as with other quinolones, should be used with extreme caution in patients predisposed to seizures, such as patients with pre-existing central nervous system lesions, concomitant treatment with fenbufen and similar non-steroidal anti-inflammatory drugs or with drugs which lower the cerebral seizure threshold, such as theophylline. *Patients with G-6-phosphate dehydrogenase deficiency:* Patients with latent or actual defects in glucose-6-phosphate dehydrogenase activity may be prone to haemolytic reactions when treated with quinolone antibacterial agents, and so levofloxacin should be used with caution. *Patients with renal impairment:* Since levofloxacin is excreted mainly by the kidneys, the dose of Levoxa should be adjusted in patients with renal impairment. *Prevention of photosensitisation:* Although photosensitisation is very rare with levofloxacin, it is recommended that patients should not expose themselves unnecessarily to strong sunlight or to artificial UV rays (e.g. sunray lamp, solarium), in order to prevent photosensitisation. *Patients treated with Vitamin K antagonists:* Due to possible increase in coagulation tests (PT/INR) and/or bleeding in patients treated with Levoxa in combination with a vitamin K antagonist (e.g. warfarin), coagulation tests should be monitored when these drugs are given concomitantly. *Psychotic reactions:* Psychotic reactions have been reported in patients receiving quinolones, including levofloxacin. In very rare cases these have progressed to suicidal thoughts and self-endangering behaviour- sometimes after only a single dose of levofloxacin. In the event that the patient develops these reactions, levofloxacin should be discontinued and appropriate measures instituted. Caution is recommended if levofloxacin is to be used in psychotic patients or in patients with history of psychiatric disease. *QT prolongation:* Very rare cases of QT interval prolongation have been reported in patients taking fluoroquinolones, including levofloxacin. Caution should be taken when using fluoroquinolones, including levofloxacin in patients with known risk factor for QT interval prolongation, like for example, elderly, uncorrected electrolyte imbalance (i.e hypokalemia, hypomagnesemia), congenital long QT syndrome, cardiovascular diseases (i.e cardiac failure, myocardial infarction, bradycardia), concomitant use of drugs known to prolong the QT interval (i.e IA and III class antiarrhythmics, tricyclic antidepressants, neuroleptics, macrolides). *Hypoglycemia:* As with all quinolones, hypoglycemia has been reported, usually in diabetic patients receiving concomitant treatment with an oral hypoglycemic agent (e.g., glibenclamide) or with insulin. In these diabetic patients, careful monitoring of blood glucose is recommended. *Peripheral neuropathy:* Sensory or sensorimotor peripheral neuropathy has been reported in patients receiving fluoroquinolones, including levofloxacin, which can be rapid in its onset. Levofloxacin should be discontinued if the patient experiences symptoms of neuropathy in order to prevent the development of an irreversible condition. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. **Interaction with other medicinal products and other forms of interaction:** *Iron salts, magnesium- or aluminium-containing antacids:* Levofloxacin absorption is significantly reduced when iron salts, or magnesium- or aluminium-containing antacids are administered concomitantly with Levoxa tablets. It is recommended that preparations containing divalent or trivalent cations such as iron salts, or magnesium- or aluminium-containing antacids should not be taken 2 hours before or after Levoxa tablet administration. No interaction was found with calcium carbonate. *Sucralfate:* The bioavailability of Levoxa tablets is significantly reduced when administered together with sucralfate. If the patient is to receive both sucralfate and Levoxa, it is best to administer sucralfate 2 hours after the Levoxa tablet administration. *Contraceptive pill:* Some antibiotics can in rare cases reduce the efficacy of contraceptive pills by interfering with bacterial hydrolysis of the steroid conjugate in the intestine and thereby the re-absorption of the unconjugated steroid. The plasma levels of the active steroid would by this means be reduced. *Theophylline, fenbufen or similar non-steroidal anti-inflammatory drugs:* No pharmacokinetic interactions of levofloxacin were found with theophylline in a clinical study. However a pronounced lowering of the cerebral seizure threshold may occur when quinolones are given concurrently with theophylline, non-steroidal anti-inflammatory drugs, or other agents which lower the seizure threshold. Levofloxacin concentrations were about 13% higher in the presence of fenbufen than when administered alone. *Probenecid and cimetidine:* Probenecid and cimetidine had a statistically significant effect on the elimination of levofloxacin. The renal clearance of levofloxacin was reduced by cimetidine (24%) and probenecid (34%). This is because both drugs are capable of blocking the renal tubular secretion of levofloxacin. However, at the tested doses in the study, the statistically significant kinetic differences are unlikely to be of clinical relevance. Caution should be exercised when levofloxacin is coadministered with drugs that effect the tubular renal secretion such as probenecid and cimetidine, especially in renally impaired patients. *Cyclosporin:* The half-life of cyclosporin was increased by 33% when coadministered with levofloxacin. *Vitamin K antagonists:* Increased coagulation tests (PT/INR) and/or bleeding, which may be severe, have been reported in patients treated with levofloxacin in combination with a vitamin K antagonist (e.g. warfarin). Coagulation tests, therefore, should be monitored in patients treated with vitamin K antagonists. *Meals:* There is no clinically relevant interaction with food. Levoxa tablets may therefore be administered regardless of food intake. *Drugs known to prolong QT interval:* Levofloxacin, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g class IA and III antiarrhytmics, tricyclic antidepressants, neuroleptics, macrolides). *Laboratory tests:* In patients treated with levofloxacin, determination of opiates in urine may give false-positive results. It may be necessary to confirm positive opiate screens by more specific methods. **Pregnancy and lactation:** *Pregnancy* - Reproductive studies in animals did not raise specific concern. However in the absence of human data and due to the experimental risk of damage by fluoroquinolones to the weight-bearing cartilage of the growing organism, Levoxa tablets must not be used in pregnant women. *Lactation* - There is no information on whether levofloxacin is excreted in breast milk. Levoxa tablets must therefore not be used during breast-feeding. Other quinolones cross into breast milk in amounts that may affect the child even at therapeutic doses. **Effects on ability to drive and use machines:** Some undesirable effects (e.g. dizziness/vertigo, drowsiness, visual disturbances) may impair the patient's ability to concentrate and react, and therefore may constitute a risk in situations where these abilities are of special importance (e.g. driving a car or operating machinery). **Undesirable effects:** Very common (≥1/10), Common (≥1/100 to <1/10), Uncommon (≥1/1,000 to <1/100), Rare (≥1/10,000 to <1/1,000) and Very rare (≤1/10,000), including isolated reports. *Infections and infestations:* Uncommon: fungal overgrowth and proliferation of other resistant microorganisms. *Blood and the lymphatic system disorders:* Uncommon: eosinophilia, leukopenia; Rare: neutropenia, thrombocytopenia; Very rare: agranulocytosis; Isolated cases: haemolytic anaemia, pancytopenia. *Immune system disorders:* Very rare: Allergic reactions (angioedema, hypotension, anaphylactic-like shock), allergic pneumonitis; Isolated cases: severe bullous eruptions such as Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome) and erythema exsudativum multiforme. Muco-cutaneous, anaphylactic /-oid reactions may sometimes occur even after the first dose. *Nervous system disorders:* Uncommon: headache, dizziness/vertigo, drowsiness, insomnia; Rare: paraesthesia, tremor, anxiety, depression, psychotic reactions with self-endangering behaviour including suicidal ideation or acts, agitation, confusion, convulsion; Very rare: sensory and sensorimotor peripheral neuropathy, visual and auditory disturbances, disturbances of taste and smell, hallucinations. *Cardiac disorders:* Rare: tachycardia; Very rare: shock (anaphylactic-like); Isolated cases: QT-interval prolongation. *Vascular disorders:* Rare: hypotension. *Respiratory, thoracic and mediastinal disorders:* Rare: bronchospasm / dyspnoea. *Gastrointestinal disorders:* Common: nausea, diarrhoea; Uncommon: anorexia, vomiting, abdominal pain, dyspepsia; Rare: bloody diarrhoea which in very rare cases may be indicative of enterocolitis, including pseudomembranous colitis; Very rare: hypoglycaemia, particularly in diabetic patients. *Hepato-biliary disorders:* Common: increase in liver enzymes (e.g. ALT / AST); Uncommon: increase in bilirubin; Very rare: liver reactions such as hepatitis. Not known: severe liver injury, including cases with acute liver failure, have been reported with levofloxacin, primarily in patients with severe underlying diseases (e.g. septicemia)." *Skin and subcutaneous tissue disorders:* Uncommon: pruritus, rash; Rare: urticaria; Very rare: photosensitisation. *Musculoskeletal, connective tissue and bone disorders:* Rare: arthralgia, myalgia, tendon disorders including tendinitis (e.g. Achilles tendon); Very rare: tendon rupture (e.g. Achilles tendon), this undesirable effect may occur within 48 hours of starting treatment and may be bilateral. Muscular weakness, which may be of special importance in patients with myasthenia gravis; Isolated cases: rhabdomyolysis. *Renal and urinary disorders:* Uncommon: increase in serum creatinine; Very rare: acute kidney failure (e.g. due to interstitial nephritis). *General disorders and administration site conditions:* Uncommon: asthenia; Very rare: fever. *Other undesirable effects which have been associated with fluoroquinolone administration include: Vascular disorders:* Hypersensitivity vasculitis. *Nervous system disorders:* Extra pyramidal symptoms and other disorders of muscular coordination. *General disorders and administration site conditions:* Attacks of porphyria in patients with porphyria. **Marketing Authorisation Holder:** Actavis Group PTC ehf. Reykjavíkurvegur 76-78, 220 Hafnarfjörður, Iceland. **This medicinal product is subject to medical prescription.**

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creating value in pharmaceuticals

Editor's word

If my memory is not turning me down, I remember that I started my editorial for 2010 with John the Savage's speech in Aldous Huxley's *Brave New World* which in turn was quoted as verbatim from Miranda's speech in Shakespeare's *The Tempest*.

But was it really a start for a Brave New World? And no, I am neither referring to the winning of the first World Cup title by Spain nor the Economic crisis of Greece or Ireland!

As I cast a bird's eye-view at 2010, I see a trial of events which could comfortably be discussed on the Eternal World Travel Network as well as the Jay Leno talk-show (one excluding the other). I am summarizing them below for your convenience:

1. The medical crisis in Haiti following the devastating earthquake in January 12;

2. The most comprehensive overhaul of the US's healthcare system since the introduction of Medicare;

3. The withdrawal from markets (including our own) of rosiglitazone (Avandia and Avandamet) and sibutramine (Reductil) and the announcement that Mixtard 30 will be gradually discontinued;

4. The introduction of the first oral drug on the US market for Multiple Sclerosis;

5. The production of the first synthetic cell;

6. The news of a new superbug (NDM-1) containing the NDM gene, which evolved in India but which is now present in the UK, Canada, Australia, Sweden and Netherlands;

7. The introduction of trials of prescription vending machines in Sainsbury's pharmacies in Sussex;

8. Not to mention the Asian Tiger Mosquito, bearer of diseases whose names (including Chikungunya and Dengue) which can be used for dyslexic testing!

Yes … 2010 was the start of a Brave New World! And 2011 will surely keep up the pace … if you stay still you can even hear Spring and Summer shouting *'Bring it on … we are bold enough to face any challenges!'*

In January 2010 I also remember writing on the possible hiring of facilities in private hospitals by the government to tackle the bed shortage at Mater Dei Hospital, also arising from acute admissions. In January 2011, I read the newspapers. And you also read the newspapers. I will not add more on this.

I felt that I should also mention (considering our current debates) that Robert Edwards was awarded the 2010 Nobel prize in medicine or physiology for his work in developing IVF. Indeed, about 4 million people were born over the past 32 years using IVF. Now, putting aside all the other slants of IVF, personally I strongly advocate such technology for couples (and just to be absolutely clear, what I mean by a couple is a naturally born male married to a naturally born female) who cannot have children. And speaking of fiscal incentives I also strongly feel that such incentives should indeed be provided, but please, please let us allocate them simply to make **each** IVF intervention cheaper for **each** couple who is indeed facing such taxing times (and yet again excuse my play of words), and not to lip-service any supposedly adoption of surplus embryos which are created through this procedure! Robert Edwards, please note.

Ian C Ellul

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Vaginal dryness?

itching
burning
soreness
painful
intercourse

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Clean. Comfortable. Convenient. Vagifem® 25µg 17ß-estradiol

Vagifem® (estradiol vaginal tablets)
Qualitative and quantitative composition: each tablet contains estradiol hemihydrate equivalent to 25 µg of estradiol. Therapeutic indication: Treatment of atrophic vaginitis due to estrogen deficiency. Contraindications: Known, past or suspected breast cancer, known or suspected oestrogen-dependent malignant tumours (e.g. endometrial cancer), undiagnosed genital bleeding, untreated endometrial hyperplasia, previous idiopathic or current venous thromboembolism (deep venous thrombosis, pulmonary embolism), known hypersensitivity to the active substances or to any of the excipients, porphyria. Special warnings: Although the dose of 17β-estradiol is low and the treatment local, systemic absorption may occur to a minor degree, especially during the initial 2 weeks. Pregnancy and lactation: Known or suspected pregnancy is a contraindication to Vagifem® therapy. No experience exists on Vagifem® therapy in lactating women; however, estrogens are excreted in milk of nursing mothers. Dosage and administration: Vagifem® is administered deeply into the vagina, using the applicator. Initial dose: 1 vaginal tablet a day for two weeks; Maintenance dose: 1 vaginal tablet twice a week; Treatment may be started on any convenient day. Side effects: The most common and well known oestrogen related adverse events are genital candidiasis or vaginitis, headache, nausea abdominal pain, abdominal distension or abdominal discomfort, dyspepsia, vomiting, flatulence, vaginal haemorrhage, vaginal discharge or vaginal discomfort, breast oedema, breast enlargement, breast pain or breast tenderness, oedema peripheral.More information can be found in the Summary of Product Characteristics. Only available on prescription!
Vagifem is a registered trademark of Novo Nordisk A/S.

Novo Nordisk Region Europe A/S, Global HRT, May 2004.

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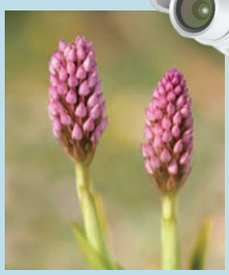
Front Page cover

Anacamptis piramidalis (Orkida piramidali; Pyramidal orchid)



Pyramidal orchid is a perennial plant growing in garigue and flowering in May-June.

Medicinal Uses

The gelatinous fluid which is formed when the tubers are boiled has been used as an emollient and to relieve diarrhoea.

Photography: **Guido Bonett** ARPS AMPS

Reference: Lanfranco G. Hxejjex Medicinali u ohrajn fil-gzejjer Maltin. Media Centre Print; Malta. 1993.

Gastrointestinal - Nutritional Problems in the Child with Neurodisability - Part I

by Thomas Attard

Neurodisability is increasingly being recognized as an important niche within pediatrics, more so since being recognized as a distinct subspeciality within the UK-STA in 2003. The spectrum of disorders encompassed in neurodisability includes learning disability, epilepsy, cerebral palsy, autistic spectrum disorders, head injury rehabilitation and neurometabolic disorders.

The child with neurodisability (ND) can be a challenge on several levels of care and it is incumbent upon the primary care physician, or pediatrician, to recognize the ramifications of the neurodisability to other systems including nutritional and gastrointestinal disorders.

This article will address the nutritional complications of ND in childhood, feeding strategies, and the impact and management of disordered motility resulting in gastroesophageal disease and constipation in these patients. The second installment of this series will address dietary modification in ND syndromes including autism.

Assessment of the nutritional status in the child with cerebral palsy can be difficult. Routine height, weight and head circumference are the basis of longitudinal growth monitoring but can be riddled with clinical and practical difficulties (Table 1). In fact, even well recorded weight-for-height percentiles will miss a significant proportion of malnourished children with cerebral palsy rendering triceps skinfold measurement preferable in this population.[1]

Foremost amongst the nutritional risks inherent to moderate and severe cerebral palsy is disordered calcium metabolism resulting in osteopenia and increased fracture risk.[2] The diagnosis of osteopenia rests upon Bone Mineral Densitometry which in children however can be problematic because of the lack of population specific norms, and more so in a contracted population as is the child with cerebral palsy. Decreased mobility, difficulty with feeds and overall malnutrition and the use of anticonvulsants tend to exacerbate the risk.

Hydrocephaly
Ischemic / Metabolic Brain Atrophy – Microcephaly
Syndromic microcephaly
Syndromic Short Stature (Example Osteogenesis)
Tendon Contractures (hips)
Scoliosis / Lordosis
Endocrine Co-morbidity (hypothyroidism)
Medications (Example steroids)
Scoliosis brace, prostheses etc.
Accessibility to hoist – weight measurement

Table 1: Difficulties and Limitations in Nutritional - Longitudinal Growth Monitoring by means of Standardized Head circumference, Weight and Height Measurement.

Management includes addressing the global nutritional status but may require calcium supplementation and modification of anticonvulsant cover.

Other trace element and vitamin deficiencies have been reported with ND including cerebral palsy, and include iron deficiency[3] and vitamin C deficiency[4]; management should focus on improving intake of fluids, proteins and vitamins. There is no consensus on the usefulness of routine multivitamin supplementation in children with ND.

Management of nutritional deficiencies in children with ND includes enteral supplementation with high-calorie drinks and modifying food preparations towards a higher calorie and more nutritious diet. Liaison with a qualified dietician is invaluable at this stage. Children with ND, notably with autism spectrum disorder can be particularly picky eaters with extreme limitation in the variety of food and in some cases limited intake overall, including fluids.[5]

In cases where oral supplementation fails it is important to identify the potential contributing factors (Table 2) in order to map out further management. Children with ND are at higher risk for swallowing dysfunction.[6]

It is important to recognize and refer children at risk to a dedicated speech therapist; in many cases a video-fluoroscopic swallow study (VFSS) may be needed

to define the risk of aspiration. In some patients assessment may result in recommendations to modify the consistency or quantity of food per feeding session; this in itself may improve the adequacy of feeding especially fluid intake.
Dysphagia and pain upon swallowing will limit oral intake and children with ND are at increased risk of gastroesophageal reflux disease[7] (GERD) and eoisinophilic esophagitis. Significant reflux will result in loss of food through emesis but, more importantly pain and food refusal. GERD in children with ND is often complex with contributing dysmotility in the foregut[8] rendering traditional medical and surgical management less likely to succeed. Proton pump inhibitors are safe

Dysfunctional swallow – slow, uncoordinated / ineffective feeds, risk of aspiration
Dental abnormalities, poor dental hygiene - caries
Dysphagia –esophagitis
Gastroesophageal Reflux Disease
Eosinophilic Esophagitis / Allergic Enteropathy
Dysmotility – delayed gastric emptying
Medication associated
Celiac Disease
Small Bowel Bacterial Overgrowth
Fecal impaction – abdominal discomfort

Table 2: Failure of oral nutritional intervention (dietary modification and caloric supplementation) in the Child with Neurodisability.

and effective in this age range but their long term safety profile may be debatable especially in view of the risk of osteopenia in the growing child with ND. Surgical intervention (fundoplication) may be required to protect the airway if severe GER complicates dysfunctional swallow, but it is imperative in this scenario to educate the parents that the risk of adverse surgical outcomes are frequent including the continued need for aggressive pharmacologic management. Specifically in children with ND, it is important to consider the possibility of Rumination Syndrome as a cause of refractory reflux symptoms.
The child with ND may have failure to thrive through malabsorptive processes or other, most notably endocrine, comorbidity. It is important therefore to carefully assess dietary intake and in select cases perform stool testing. Both Celiac Disease and Small Bowel Bacterial Overgrowth are two malabsorptive processes that appear to be more prevalent in children with ND including CP[9] and may warrant diagnostic testing including endoscopy with biopsy or aspirate.
In those children with ND who appear to be failing to thrive or who are irreversibly malnourished despite oral supplementation alone, discussion of tube feeds is the obvious next step. These are usually emotionally charged subjects even though the parents may already have clear indications that this is necessary.[10] It is important to stress that a period of supplemental feeds via nasogastric tube should prove that a more definitive procedure, i.e. gastrostomy is indicated and will achieve the desired improved nutritional status: it is not unusual for supplemental NG feeds to exacerbate previously unrecognized reflux. It is equally important to stress that neither nasogastric nor eventually gastrostomy feeds, will preclude continued oral feeds. In practice, families tend to achieve more harmonious or at least, less stressful interactions around mealtimes as both the onus of delivering adequate calories, often from non-preferred foods is removed from the parents.[11]
Another manifestation of the complex dysmotility processes in children with ND especially CP is the high prevalence of constipation in this subpopulation. There are multiple additional potential factors, some reversible, that contribute towards constipation in this population (Table 3).

Dysautonomia - dysmotility
Immobility
Fluid deprivation
Medications
Low fiber diet
Special diets (Example ketogenic diet)

Table 3: Potential Factors Contributing Towards the Development of Constipation in the Child with Cerebral Palsy.

Functional constipation, and if untreated, retentive fecal incontinence (encopresis) is also more common in children with autism[12] and other milder neurologic and behavioral abnormalities like Attention Deficit Hyperactivity Disorder. In these individuals it is important to recognize that although the constipation – overflow diarrhea is rooted in the child's behavioral disorder, its natural history is such that it evolves into a disorder that requires long-term aggressive medical management along with behavioral modification in order to be definitively treated. The reader is referred to our earlier article on the subject.
In summary we have herein reviewed some of the gastrointestinal-nutritional sequelae of neurodisability in children. In this more vulnerable subpopulation of patients, optimized nutrition cannot be over-emphasized and a multidisciplinary coordinated effort can resolve some of the difficulties that prevent our patients from achieving their full potential.

References
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COMPREHENSIVE POWER TO ADVANCE TYPE 2 DIABETES TREATMENT

GALVUS is a DPP-4 inhibitor that improves glycemic control through powerful islet enhancement[1]

EUCREAS is the combination of a DPP-4 inhibitor, GALVUS, and metformin[2]

Galvus® 50mg (vildagliptin) tablets

PRESENTATION: Each tablet contains 50 mg of vildagliptin **INDICATIONS:** For the treatment of type 2 diabetes mellitus: As dual oral therapy in combination with - metformin, in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin, - a sulphonylurea, in patients with insufficient glycaemic control despite maximal tolerated dose of a sulphonylurea and for whom metformin is inappropriate due to contraindications or intolerance, - a thiazolidinedione, in patients with insufficient glycaemic control and for whom the use of a thiazolidinedione is appropriate. **DOSAGE AND ADMINISTRATION:** In combination with metformin or thiazolidinedione 100mg daily, administered in two divided doses of one 50 mg in the morning and one 50 mg in the evening. In combination with sulphonylurea, 50 mg once daily in the morning. Galvus can be administered with or without a meal. Doses greater than 100 mg are not recommended. Galvus is not recommended for use in patients less than 18 years old. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the excipients **PRECAUTIONS/WARNINGS** Galvus should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. Galvus is not recommended in patients with moderate or severe renal impairment or in haemodialysis patients with end-stage renal disease. Galvus is not recommended in patients with hepatic impairment, including patients with pre-treatment ALT or AST >3x the ULN. Liver function tests should be performed prior to treatment initiation, at three month intervals during the first year and periodically thereafter. Should an increase in AST or ALT of 3xULN or greater persist, withdrawal of Galvus therapy is recommended. Patients who develop jaundice or other signs suggestive of liver dysfunction should discontinue Galvus. Vildagliptin should be used with caution in patients with congestive heart failure of New York Heart Association (NYHA) functional class I-II and is not recommended in patients with NYHA functional class III-IV. Routine monitoring of diabetic patients for skin disorders such as blistering or ulceration is recommended. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. **PREGNANCY AND LACTATION:** Galvus should not be administered during pregnancy or lactation. **INTERACTIONS:** Vildagliptin has a low potential for drug interactions. No clinically relevant interactions with other antidiabetics (glyburide, pioglitazone, metformin), amlodipine, digoxin, ramipril, simvastatin, valsartan or warfarin were observed after co-administration with vildagliptin. As with other oral antidiabetic medicines, the hypoglycaemic effect of vildagliptin may be reduced by certain active substances, including thiazides, corticosteroids, thyroid products and sympathomimetics. **UNDESIRABLE EFFECTS:** Rare cases (>1/10,000 to <1/1,000) angioedema, hepatic dysfunction (including hepatitis). *Monotherapy:* Common (>1/100 to <1/10): dizziness, Uncommon (>1/1,000 to <1/100): headache, constipation, arthralgia, hypoglycaemia, oedema peripheral. Very rare (<1/10,000): URTI, nasopharyngitis. *Combination with metformin:* Common: tremor, headache, dizziness, nausea, hypoglycaemia. Uncommon: fatigue. *Combination with sulphonylurea:* Common: tremor, headache, dizziness, asthenia, hypoglycaemia. Uncommon: constipation. Very rare: nasopharyngitis. *Combination with Thiazolidinedione:* Common: weight increase. oedema peripheral, Uncommon: headache, asthenia, hypoglycaemia. **PACK SIZES:** 7, 28 tablets **MARKETING AUTHORISATION NUMBERS:** EU/1/07/414/001, 003. **MARKETING AUTHORISATION HOLDER:** Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom. **LEGAL CATEGORY:** POM Before prescribing please refer to Summary of Product Characteristics (SmPC). Full prescribing information is available on request from Novartis Pharma Services Inc, Representative Office Malta, P.O. Box 124, Valletta, VLT 1000, Malta. Tel +356 22983217. 2011-MT-01 GAL JAN 2011

Eucreas® (vildagliptin/metformin hydrochloride) film-coated tablets

PRESENTATION: Each 50 mg/850 mg film-coated tablet contains 50 mg of vildagliptin and 850 mg metformin hydrochloride. Each 50 mg/1000 mg film-coated tablet contains 50 mg of vildagliptin and 1000 mg metformin hydrochloride. **INDICATIONS:** Eucreas is indicated in the treatment of type 2 diabetes mellitus patients who are unable to achieve sufficient glycaemic control at their maximally tolerated dose of oral metformin alone or who are already treated with the combination of vildagliptin and metformin as separate tablets. **DOSAGE AND ADMINISTRATION:** The recommended daily dose should be based on the patient's current regimen of vildagliptin and /or metformin hydrochloride. The usual dose is 50 mg/850 mg or 50 mg/1000 mg twice daily one tablet in the morning and the other in the evening. Eucreas should be taken with or just after food. Doses of vildagliptin greater than 100 mg are not recommended. Patients ≥ 65 taking Eucreas should have their renal function monitored regularly. Eucreas is not recommended for use in patients less than 18 years old. For use in renal or hepatic impairment, see contraindications and precautions below or refer to the SmPC for more information. **CONTRAINDICATIONS:** Hypersensitivity to vildagliptin or metformin hydrochloride or to any of the excipients. Diabetic ketoacidosis or diabetic pre-coma. Renal failure or renal dysfunction defined as creatinine clearance < 60 ml/min. Acute conditions with the potential to alter renal function e.g. dehydration, severe infection, shock or intravascular administration of iodinated contrast agents. Acute or chronic disease which may cause tissue hypoxia e.g. cardiac or respiratory failure, recent myocardial infarction, shock. Hepatic impairment. Acute alcohol intoxication, alcoholism, Lactation **PRECAUTIONS/WARNINGS:** Eucreas should not be used in patients with type 1 diabetes. Due to the risk of lactic acidosis, renal function could be monitored at least once yearly in patients with normal renal function and at least two to four times/year in patients with serum creatinine at the upper limit of normal and in elderly patients. Eucreas is not recommended in patients with hepatic impairment, including patients with pre-treatment ALT or AST >3x the ULN. LFT's should be performed prior to treatment initiation, at three month intervals during the first year and periodically thereafter. Should an increase in AST or ALT of 3x ULN or greater persist, withdrawal of Eucreas therapy is recommended. Patients who develop jaundice or other signs suggestive of liver dysfunction should discontinue Eucreas. Vildagliptin should be used with caution in patients with congestive heart failure of New York Heart Association (NYHA) functional class I-II and is not recommended in patients with NYHA functional class III-IV. Metformin is contraindicated in patients with heart failure, therefore Eucreas is contraindicated in this population. Routine monitoring of diabetic patients for skin disorders such as blistering or ulceration is recommended. As Eucreas contains metformin, treatment should be discontinued 48 hours before elective surgery with general anaesthesia and not usually resumed earlier than 48 hours afterwards. The IV administration of iodinated contrast agents can lead to renal failure. Therefore due to metformin active ingredient, Eucreas should be discontinued prior to or at the time of the test and not reinstituted until 48 hours afterwards and only after renal function has been re-evaluated and found to be normal. **PREGNANCY AND LACTATION:** Eucreas should not be administered during pregnancy or lactation. **INTERACTIONS:** Vildagliptin has a low potential for drug interactions. No clinically relevant interactions with other antidiabetics (glyburide, pioglitazone, metformin), amlodipine, digoxin, ramipril, simvastatin, valsartan or warfarin were observed after co-administration with vildagliptin. Interactions with metformin hydrochloride that are not recommended include alcohol, cationic active substances e.g. cimetidine and intravascular administration of iodinated contrast media. Combinations requiring caution include metformin hydrochloride with medicines tending to produce hyperglycaemic activity e.g. glucocorticoids, beta agonists and diuretics. The dose of antihyperglycaemic medicinal products may need to be adjusted in combination with ACE inhibitors. **UNDESIRABLE EFFECTS:** Rare cases (≥1/10,000 to <1/1,000) angiodema, hepatic dysfunction (including hepatitis) have been reported with vildagliptin. *Vildagliptin Monotherapy:* Common (>1/100 to <1/10): dizziness, Uncommon (>1/1,000 to <1/100): headache, constipation, arthralgia, hypoglycaemia, oedema peripheral. Very rare (<1/10,000): URTI, nasopharyngitis. *Metformin monotherapy:* Very common (≥1/10) Nausea, vomiting, diarrhoea, abdominal pain and loss of appetite. Common: metallic taste. *Combination vildagliptin with metformin:* Common: tremor, headache, dizziness, nausea, hypoglycaemia. Uncommon: fatigue. For a full list fo Adverse reactions, please refer to the SmPC. **PACK SIZES:** 30, 60 film-coated tablets **MARKETING AUTHORISATION NUMBER:** EU/1/07/425/002–003, EU/1/07/425/008-009. **MARKETING AUTHORISATION HOLDER:** Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom. **LEGAL CATEGORY:**POM Consult full Summary of Product Characteristics (SmPC) before prescribing. Full prescribing information is available upon request from: Novartis Pharma Services Inc, Representative Office Malta, P.O. Box 124, Valletta VLT 1000, Malta. Tel +356 22983217 2011-MT-01 EUC Jan 2011

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Galvus® vildagliptin

1. Novartis Europharm Ltd. Galvus® Summary of Product Characteristics
2. Novartis Europharm Ltd. Eucreas® Summary of Product Characteristics

Eucreas® vildagliptin/metformin

GAL Ad1 02/11 MT

Antibiotics: Using Them Judiciously

by Tanya Melillo Fenech

A third of all primary care consultations are due to infectious diseases and more than half of these are due to respiratory tract infections. Respiratory infections are among the most frequent reasons for prescribing antibiotics even though the majority of upper respiratory tract infections are of viral origin and antibiotics are known to have minimal effect against them. In fact many studies show that over 75% of cases of otitis media and sinusitis and more than half of all pharyngo-tonsillitis and acute bronchitis are treated with antibiotics.

There is obviously seasonal variation in the use of antibiotics as maximum consumption of antibiotics correlates with influenza activity. Research has shown that the excessive use of antibiotics has contributed to the emergence and spread of antibiotic-resistant bacteria in the community. Resistance to antibiotics is high among Gram-positive and Gram-negative bacteria. Countries with the highest per-capita antibiotic consumption have the highest frequency and patterns of resistance.
Studies have shown significant differences in prescription of antibiotics between countries and also between physicians in the same country. Factors contributing to these differences include the doctor's patient load, years of practice, limited consultation time, characteristics of the prescribers such as their age and sex, as well as patients' employment status and their demand for antibiotics.
It has been suggested that doctors who are more familiar with their patients adopt a more subjective way of prescribing and are more influenced by the patient's expectations and requests, rather than following clinical practice guidelines.
One of the main problems general practitioners face on a daily basis is that the information obtained from the clinical history and physical examination does not provide enough information to enable them
to conclude whether the aetiology of the infection is bacterial or not and so when in doubt, antibiotics are prescribed. Moreover, family doctors tend to overestimate the proportion of their patients who expect to
receive antibiotics. To add to all this, those patients who indeed expect to receive antibiotics, often have expectations based on false assumptions or experiences from previous visits. Another aspect that plays a part in prescribing antibiotics is the different weight doctors give to different signs and symptoms. Many doctors give greater weight to purulent sputum in bronchitic disease while scientific evidence shows that purulence is a natural part of the evolution of bronchitis and that its presence does not imply a bacterial superinfection in patients with no chronic lung disease.

Furthermore, during emergencies, such as influenza epidemics, doctors have to deal with high work loads and with limited available consultation time to make quick decisions and it takes less time to write a prescription than to give a patient a detailed explanation as to why antibiotic treatment is not indicated.
Various strategies have proven useful in promoting more prudent use of antibiotics in primary care and these include:

• Delayed prescription of antibiotics in non-serious infections of suspected viral aetiology in patients who express a preference for antibiotics: This consists in telling patients to withhold from taking antibiotics unless symptoms persist or worsen after a few days. Various studies performed in the UK have found a reduction in the use of antibiotics when delayed prescription is implemented in uncomplicated respiratory illnesses.

• Improving communication skills between the family doctor and his patients: Doctors need to communicate clearly with their patients about the evolution of the infectious process they are suffering from. In one study, McFarlane et al. observed that adults who visit their doctor because of coughing revisit less if they receive clear information on the natural history of the disease.

• Educate our patients on misconceptions on antibiotics: A Eurobarometer survey done in 2009 in EU member states clearly showed that still many Europeans including Maltese people have many misconceptions on antibiotics use. 53% of Europeans wrongly think that antibiotics kill viruses and that they are affective against colds and influenza. The survey showed that respondents from Southern European union countries are the ones most likely to use antibiotics. The Italians (57%), seconded by the Maltese (55%) and then by Spain (53%) and Romania (51%) stated that they have taken antibiotics in the last year. When asked for reasons for taking antibiotics, the Maltese gave the highest score (31%) from all the EU countries for sorethroats, and 26% for influenza.

• The use of rapid diagnostic tests in the doctor's office: These include rapid antigenic tests for the diagnosis of pharyngitis by group A beta-haemolytic streptococcus and the determination of C-reactive protein in capillary blood.

A reduction in the consumption of antibiotics can lead to a decline in the resistance of the microorganisms. This has been seen in a number of countries. Antibiotic use for prevention purposes should be avoided except in the specific cases such as for contacts of bacterial meningitis, latent tuberculosis infection, anatomical or functional asplenia, and contacts with pertussis.

Antibiotic resistance remains a serious public health issue as it causes a threat to patient safety, reducing options for treatment and increasing lengths of hospital stay, as well as increasing patient morbidity and mortality. It is our responsibility as doctors to raise awareness amongst our patients on the prudent use of antibiotics and to practice what we preach by using antibiotics judiciously.

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Onbrez Breezhaler (indacaterol) inhalation powder, hard capsules
PRESENTATION: Onbrez Breezhaler 150mcg and 300mcg inhalation powder hard capsules containing indacaterol maleate, and separate Onbrez Breezhaler inhaler. **INDICATIONS:** For maintenance bronchodilator treatment of airflow obstruction in adult patients with chronic obstructive pulmonary disease (COPD). **DOSAGE AND ADMINISTRATION:** Recommended dose is the inhalation of the content of one 150mcg capsule once a day, administered at the same time of the day each day, using the Onbrez Breezhaler inhaler. Capsules must not be swallowed. Dose should only be increased on medical advice. The inhalation of the content of one 300mcg capsule once a day has been shown to provide additional clinical benefit with regard to breathlessness, particularly for patients with severe COPD. Maximum dose is 300mcg once daily. No dose adjustment required in elderly patients, for patients with mild and moderate hepatic impairment or for patients with renal impairment. No data available for use in patients with severe hepatic impairment. No relevant use in the paediatric population. **CONTRAINDICATIONS:** Hypersensitivity to the active substance, to lactose or to any of the other excipients. **WARNINGS/PRECAUTIONS:** ***Asthma:*** ♦ONBREZ BREEZHALER SHOULD NOT BE USED IN ASTHMA. ***Paradoxical bronchospasm:*** ♦ If paradoxical bronchospasm occurs Onbrez Breezhaler should be discontinued immediately and alternative therapy substituted. ***Deterioration of disease:*** ♦ Not indicated for treatment of acute episodes of bronchospasm, i.e. as rescue therapy. ***Systemic effects:*** ♦Indacaterol should be used with caution in patients with cardiovascular disorders (coronary artery disease, acute myocardial infarction, cardiac arrhythmias, hypertension), in patients with convulsive disorders or thyrotoxicosis, and in patients who are unusually responsive to beta2-adrenergic agonists. ***Cardiovascular effects:*** ♦ Indacaterol may produce a clinically significant cardiovascular effect in some patients as measured by increases in pulse rate, blood pressure, and/or symptoms, ECG changes. In case such effects occur, treatment may need to be discontinued. ***Hypokalaemia:*** ♦ Beta2-adrenergic agonists may produce significant hypokalaemia in some patients, which has the potential to produce cardiovascular effects. In patients with severe COPD, hypokalaemia may be potentiated by hypoxia and concomitant treatment which may increase the susceptibility to cardiac arrhythmias. ***Hyperglycaemia:*** ♦Inhalation of high doses of beta2-adrenergic agonists may produce increases in plasma glucose. Upon initiation of treatment with Onbrez Breezhaler plasma glucose should be monitored more closely in diabetic patients. ♦During clinical studies, clinically notable changes in blood glucose were generally more frequent by 1-2% on Onbrez Breezhaler at the recommended doses than on placebo. Onbrez Breezhaler has not been investigated in patients with not well controlled diabetes mellitus. ***Pregnancy and Lactation:*** ♦No data available from the use of indacaterol in pregnant women. Onbrez Breezhaler should only be used during pregnancy if the expected benefits outweigh the potential risks. ♦Not known whether indacaterol / metabolites are excreted in human milk. A decision must be made whether to discontinue breast-feeding or discontinue Onbrez Breezhaler therapy, taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. **INTERACTIONS:** ♦Concomitant administration of other sympathomimetic agents may potentiate the undesirable effects of Onbrez Breezhaler. Onbrez Breezhaler should not be used in conjunction with other long-acting beta2-adrenergic agonists or medicinal products containing long-acting beta2-adrenergic agonists. ♦Concomitant hypokalaemic treatment with methylxanthine derivatives, steroids, or non-potassium-sparing diuretics may potentiate the possible hypokalaemic effect of beta2-adrenergic agonists, therefore use with caution. ♦Indacaterol should not be given together with beta-adrenergic blockers (including eye drops) as these may weaken or antagonise the effect of beta2-adrenergic agonists. Where required, cardioselective beta-adrenergic blockers should be preferred, although they should be administered with caution. ♦Inhibition of the key contributors of indacaterol clearance, CYP3A4 and P-gp, does not raise any safety concerns given the safety experience of treatment with Onbrez Breezhaler. ♦Indacaterol has not been shown to cause interactions with co-medications. **ADVERSE REACTIONS:** ♦The most common adverse reactions with Onbrez Breezhaler are: nasopharyngitis, upper respiratory tract infection, sinusitis, diabetes mellitus and hyperglycaemia, headache, ischaemic heart disease, cough, pharyngolaryngeal pain, rhinorrhoea, respiratory tract congestion, muscle spasm, peripheral oedema. ♦Uncommon: paraesthesia, atrial fibrillation and non-cardiac chest pain. ♦Please refer to SmPC for a full list of adverse events for Onbrez Breezhaler. **LEGAL CATEGORY:** **POM PACK SIZES:** Onbrez Breezhaler 150mcg - carton containing 10 or 30 capsules and one Onbrez Breezhaler inhaler. Onbrez Breezhaler 300mcg - carton containing 30 capsules and one Onbrez Breezhaler inhaler **MARKETING AUTHORISATION HOLDER:** Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom. **MARKETING AUTHORISATION NUMBERS:** EU/1/09/593/001, 002, 007 Please refer to Summary of Product Characteristics (SmPC) before prescribing. Full prescribing information is available on request from Novartis Pharma Services Inc, Representative Office P.O Box 124, Valletta, VLT 1000 Malta. Tel: +356 22983217 2010-MT-01-ONB-16-Jun-2010

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References:
1. Cazzola M, Matera MG. Novel long-acting bronchodilators for COPD and asthma. *Br J Pharmacol*. 2008;155:291-299.
2. Novartis Europharm Ltd. Onbrez® Breezhaler® Summary of Product Characteristics

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Herbal Medicine:
A Legal Perspective

by Everaldo Attard

Introduction

Although within the European Union, herbal medicines are considered as alternative medicines or are used in adjunct therapies; their use is considered as an important component of the European health care system. This is due to the fact that herbal medicine forms part of the European tradition. In spite of the diversity of opinions between Member States, herbal medicines used in different therapies should be made available to all European citizens. However, although the efficacy of certain medicines is rather disputable, the European Commission aims at safeguarding the European consumer by ensuring that these medicines are safe and of an adequate quality.

Is the product a medicine?

A medicine is defined as a substance or group of substances that correct or re-establish balance within the body. If this adjustment is on a physiological basis, the product may fall under the Food Supplements Directive (CD 2002/46/EC)[1] or the Cosmetics Directive (CD 76/768/EC)[2]. Products that prevent diseases have been in great dispute and therefore such products, which may be classified as either medicinal products and/or food supplements, are usually subjected to a case by case assessment. These products are also called borderline products, until they are classified as medicinal or non-medicinal products.

What types of medicines do exist?

There are different types of medicines, primarily depending on their nature and purpose of use. If the product is derived from one or more herbal substances, then the product may be considered as a herbal medicinal product. If this product is a synthetic chemical entity, a highly purified extract or single constituent from a natural source (plant, animal or mineral origin), the product should satisfy the criteria laid under Council Directive 2001/83/EC to be granted a marketing authorisation[3]. Another category of herbal medicines that fall under the 2001/83/EC Directive are homeopathic medicinal products, that however have to be presented as diluted (potentised) medicines.

Chemical entities (modern medicines) are regulated under Council Directive 2001/83/EC and all subsequent amendments. These include chemical synthetics, homeopathic medicines and isolated chemicals derived from medicinal plants. In the manufacture and marketing authorisation of herbal medicines, European manufacturers and wholesale distributors faced several difficulties to fulfil the criteria laid in this Council Directive in order to market their products. Due to a long standing history of use, the requirement that a medicinal product should satisfy the proof of clinical efficacy could not be fulfilled with herbal medicines. This places herbal medicines in a different category from chemical entities. In fact, a parliament legislative resolution was issued in November 2002 as a proposal to amend Council Directive 2001/83/EC to take into consideration this important aspect which otherwise will put the herbal industry at a halt. There was the need to consider herbal medicines as a group of medicinal products of their own, which should satisfy the safety and quality requirements, but could be exempted from the efficacy requirements. As a matter of fact, a new Council Directive 2004/24/EC[4] was issued dealing specifically with herbal medicinal products with known traditional uses.

With this, herbal medicines were categorised into:
- Herbal medicines with a long-history of medicinal usage within the European Community, the so-called Traditional Herbal Medicinal Products (THMPs), and
- Herbal medicines which have been tested clinically and showed clinical efficacy, the so-called Herbal Medicines with a Well-Established medicinal Use (WEU).

In fact, these two categories fall explicitly under different Council Directives.

Herbal medicinal products are further categorised into:
- Herbal Substances. These mainly include unprocessed herbal materials and are defined by the binomial botanical name and plant part used. These include also algae, fungi, lichen and certain exudates, in their fresh or dried state.
- Herbal Preparations. These include processed or treated herbal substances, employing a certain degree of transformation, such as extraction, expression, fractionation, distillation, fermentation or concentration. Such preparations include comminuted or powdered herbal substances, essential oils, plant extracts, tinctures and other herbal formulations.

Conclusion

Once a product fulfils these conditions, the HMP can be identified as a THMP or a herbal with a WEU. A decision tree5 has been prepared to facilitate classification. In most cases, there is no clear distinction as at what dose one should consider the product to be a HMP or a food supplement. Although there is a list of herbal substances that are exclusively found in HMP, in other cases, assessment should be carried out on a case per case basis.

References

1. Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, Official Journal L 183; 51-57. 2. Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products, Official Journal L 262; 169. 3.Legal Notice 386 of 2005. MEDICINES ACT, 2003. Wholesale Distribution of Medicinal Products Regulations, 2005; B 5528 – B5532. 4.Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, Official Journal L 311; 67-128.5. Decision tree for the classification of traditional herbal medicinal products and herbal medicines with a well-established use at http://staff.um.edu.mt/eatt1/THMPs/

Introducing Wine Tasting Events

TheSynapse MedClub is proposing to start dining and blind wine tasting sessions in the very near future. There will be no embarrassing pressure on participants to guess wine type, and the scope is to learn how to taste wine, assess its quality and determine personal wine style preferences. The learning process will also endeavour to demystify the complexities of the wine world.

The pattern of the sessions will be based on the experience gained at "Il-Qatra" Wine Club, which started 10 years ago with 12 members and now has 70. Wine was invented to compliment meals, and therefore should be assessed and enjoyed with a proper meal and not just cheese and biscuits. The sessions will be planned and tutored by colleague Albert Cilia-Vincenti, one of the founding committee members of "Il-Qatra". The format will be a quality dinner accompanied by blind tasting of four wines.

The dinners will be held at the Radisson Blu in St Julians, in the same restaurant that the Qatra Wine Club holds its sessions, and where the level of service for such a function is well established. The cost will be €65 per member (€110 for member & partner) to include everything. Negotiations are also ongoing with ITS with a view of enjoying a similar quality dinner at a cheaper cost. Before going ahead with these sessions, the TheSynapse MedClub needs to know whether any members are actually interested. If you are interested kindly send an email on mpl@thesynapse.net or phone 21453973.

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COMPETITION CORNER – ISSUE 6/10

Last issues' challenge answers

1. According to the WHO, a particular disease has been eradicated completely lately. This is only the 2nd time that such a feat has been accomplished (after the eradication of smallpox 30 years ago). Name the disease: **Rinderpest**
2. Which society has issued Clinical Practice Guidelines during the past few months? **The European Society of Cardiology**

The **winner** is:
Dr Paul Gatt (2 One-day membership at Athenaeum Spa)

TheSynapse team would like to congratulate the winner and thank the sponsors of these competitions.

THIS MONTH'S CHALLENGE

The answers to all questions can be found in issue 6/10.Those who get a correct answer will participate in a draw where the first two drawn names will each win a 1 day membership to the Corinthia Athenaeum Spa, Attard.

1. Mention the name of the interviewee:

_____

2. What is the estimated sum needed to implement a local National Sexual Health Policy?

_____

Fill in your details

Name

Address

Email

Mobile

Kindly submit the answers by mail by filling the form on this page addressed to The Professional Services Centre, 3 Guzi Cutajar Street, Dingli, DGL 1201 or submit your answers on- line on www.thesynapse.net/quiz. All submissions will participate in a draw.
You have up to the 15th March 2011 to submit your answers.

Health Promotion Quiz

Name the campaign launched by the The Health Promotion and Disease Prevention Directorate over the Christmas period:

_____

The answer can be found in Issue 6/10. The first drawn name will get a 3 month membership for a Parent and Kid at Spinach Fitness Club, Malta's first kids' gym – Melita Training Grounds, Pembroke. The gym may be contacted at www.spinachfitness.com or 21/79383740.

Kindly submit the answers by mail by filling the form on this page addressed to The Professional Services Centre, 3 Guzi Cutajar Street, Dingli, DGL 1201 or submit your answers on-line on www.thesynapse.net/hpdquiz. All submissions will participate in a draw.
You have up to the 15th March 2011 to submit your answers

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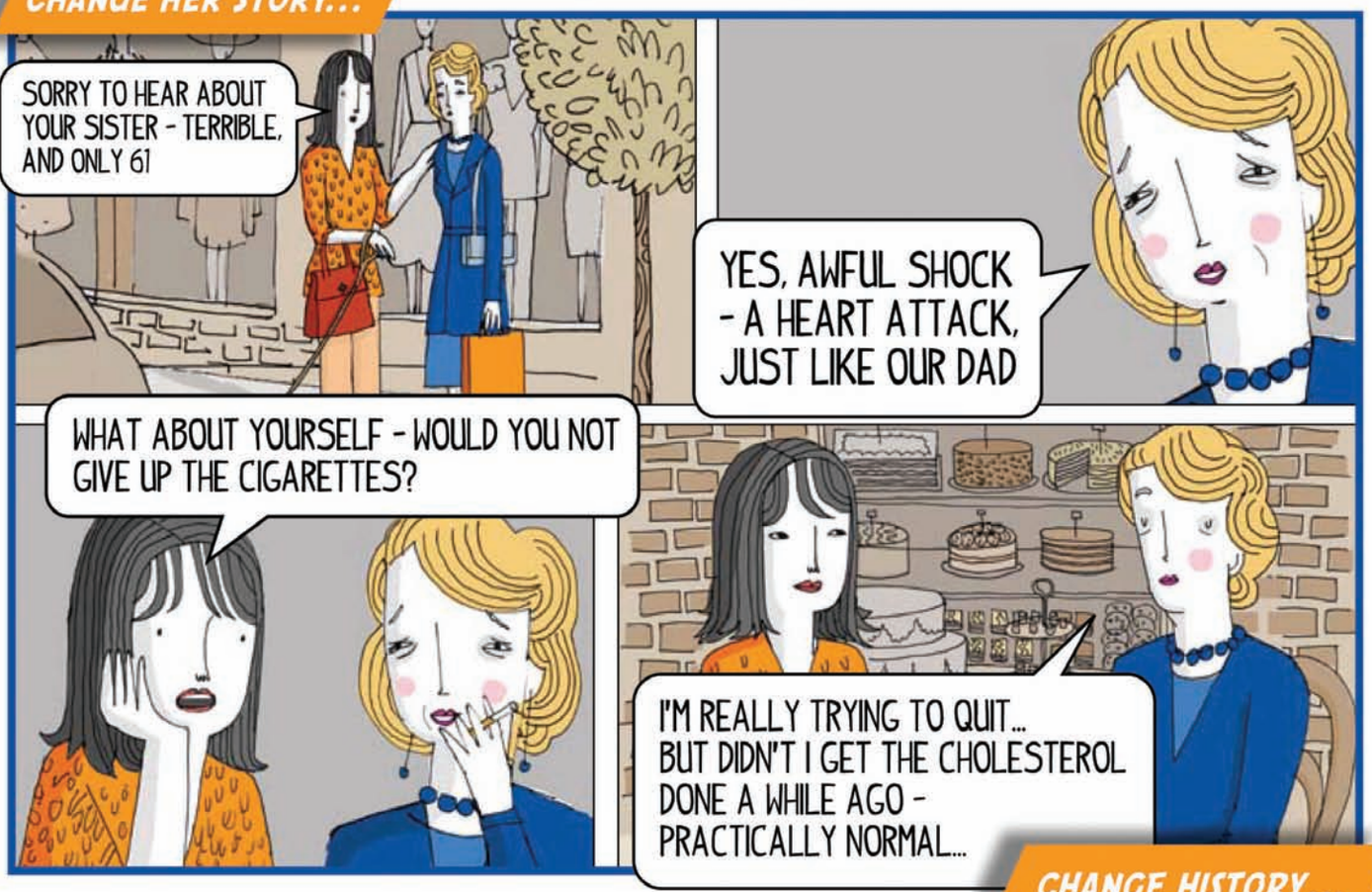

CHANGE HISTORY...

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IN CONJUNCTION WITH CORRECTION OF HER OTHER RISK FACTORS*

† NOTE: JUPITER used CRESTOR 20mg. The recommended start dose for hypercholesterolaemia is 5 or 10mg (refer to SPC)

* modifiable risk factors include smoking cessation, exercise, weight loss and diet

Abbreviated Prescribing Information CRESTOR® Refer to the full Summary of Product Characteristics (SPC) before prescribing **Presentation:** Film-coated tablets containing 5mg, 10mg, 20mg, or 40mg of rosuvastatin. **Indications:** In patients unresponsive to diet and other non-pharmacological measures, CRESTOR is indicated for primary hypercholesterolaemia (including heterozygous familial hypercholesterolaemia), homozygous familial hypercholesterolaemia, or mixed dyslipidaemia. Prevention of cardiovascular events in patients who are estimated to have a high risk for a first cardiovascular event as an adjunct to correction of other risk factors. **Dosage:** *Treatment of hypercholesterolaemia:* Recommended start dose is 5 or 10 mg daily (including those being switched from other statins). Choice of start dose should take into account the individual patient's cholesterol level and future cardiovascular risk and potential risk for adverse reactions. A dose adjustment to the next dose level can be made after 4 weeks, if necessary. Maximum daily dose is 40mg. A final titration to the maximum dose of 40 mg should only be considered in patients with severe hypercholesterolaemia at high cardiovascular risk (in particular those with familial hypercholesterolaemia), who do not achieve their treatment goal on 20 mg, and in whom routine follow-up will be performed. Specialist supervision is recommended when the 40 mg dose is initiated – refer to SPC. Doses may be given at any time of the day with or without food. *Elderly:* A start dose of 5 mg is recommended in patients >70 years. No other dose adjustment is necessary in relation to age. *Dosage in patients with renal insufficiency:* Recommended start dose is 5 mg in patients with moderate renal impairment (creatinine clearance <60 ml/min). The 40 mg dose is contraindicated in patients with moderate renal impairment. 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Prevention of cardiovascular events: the dose used in the cardiovascular events risk reduction study was 20mg. **Contra-indications:** Hypersensitivity to any of the ingredients; active liver disease or unexplained persistent elevations in serum transaminases and any serum transaminase > 3 x upper limit of normal; severe renal impairment; myopathy; concomitant ciclosporin; pregnancy and breast-feeding; women of child-bearing potential not using contraception. In addition CRESTOR 40mg is contraindicated with concomitant fibrates, and in patients with predisposing factors for myopathy/rhabdomyolysis including patients of Asian origin (refer to SPC for more information). **Warnings and precautions:** *Renal effects:* Proteinuria which in most cases is transient or intermittent has been observed. Assessment of renal function should be considered during routine follow-up of patients treated with CRESTOR 40 mg. *Muscle effects:* Patients with signs and symptoms of myopathy should be asked to report their symptoms immediately and should have their creatine kinase (CK) levels monitored. CRESTOR should be discontinued if CK levels are markedly elevated or, if muscle symptoms are severe and cause daily discomfort. Risk of myositis and myopathy may increase when administered with certain other drugs (refer to SPC), combination of CRESTOR with gemfibrozil is not recommended for this reason and the benefit versus risk considered when combining CRESTOR with fibrates and niacin. Very rare cases of rhabdomyolysis have been reported with the use of ezetimibe and HMG-CoA reductase inhibitors. CRESTOR, as with other HMG-CoA reductase inhibitors, should be prescribed with caution in patients with pre-disposing factors for myopathy or rhabdomyolysis (see SPC), and if CK levels are significantly elevated at baseline, treatment should not be started. CRESTOR should not be used in patients with an acute, serious condition suggestive of myopathy or predisposing to the development of renal failure secondary to rhabdomyolysis. Rarely, rhabdomyolysis, occasionally associated with impairment of renal function has been reported with all doses and in particular doses >20mg. *Liver effects:* CRESTOR should be used with caution in patients with a history of liver disease and/or alcoholism. Liver function tests should be carried out, prior to, and 3 months following the initiation of treatment. CRESTOR should be discontinued or the dose reduced if the level of serum transaminases is greater than 3-times the upper limit of normal. 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Other usually transient side effects: elevation in CK levels, proteinuria. Other adverse events listed as unknown: diarrhoea, Stevens-Johnson syndrome, oedema, cough and dyspnoea. The following adverse events have been reported with some statins: depression, sleep disturbances including insomnia and nightmares, sexual dysfunction and exceptional cases of interstitial lung disease, especially with long term therapy. **Legal Category:** POM. **Marketing Authorisation Number (s):** PA 970/57/1-4. **Marketing Authorisation Holder:** AstraZeneca UK Ltd, 600 Capability Green, Luton, LU1 3LU, UK. Further information is available on request from: AstraZeneca Pharmaceuticals (Ireland) Ltd., College Park House, 20 Nassau Street, Dublin 2 Telephone: (01) 6097100; Updated 06/10 CRESTOR is a trademark of the AstraZeneca group of companies. Licensed from Shionogi & Co Ltd, Osaka, Japan. **Date of preparation:** July 2010. **URN:** 10/0396.

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Minimising your risk of cancer - World Cancer Day

by Charmaine Gauci

Cancer is a leading cause of death around the world. WHO estimated that 84 million people will die of cancer between 2005 and 2015 (without intervention). Each year on 4 February, WHO supports the International Union Against Cancer to promote ways to ease the global burden of cancer. Obviously, preventing cancer and raising quality of life for cancer patients are recurring themes. Local data from 1996-2008 show that there are increasing trends in incidence when all cancers are included together, for both genders. There were 401.2 new cases per 100,000 people during 2008. However the overall age-standardised-rate remains below the European average rate.

The commonest cancer in females are breast and in males colorectal cancer and prostate cancer. Locally, there were 837 deaths from these cancers in 2009. It has been estimated that more than 30% of cancer deaths can be prevented. Many aspects of general health can be improved, and certain cancers avoided, if one adopts a healthier lifestyle.

Key points which one should communicate to patients include:

1. Do not smoke. Smoking is the largest single cause of premature death;
2. Keep a healthy weight;
3. Undertake brisk, physical activity every day;
4. Make sure you consume a variety of fruit and vegetables eating at least five servings daily. You need to reduce intake of animal fat;
5. If you drink alcohol, whether beer, wine or spirits, moderate your consumption to a minimum;
6. Care must be taken to avoid excessive sun exposure. It is specifically important to protect children and adolescents. For individuals who have a tendency to burn in the sun active protective measures must be taken throughout life;
7. Apply strictly regulations aimed at preventing any exposure to known cancer-causing substances. Follow all health and safety instructions on substances which may cause cancer.

The Ministry for Health, the Elderly and Community Care will shortly be launching the National Cancer Plan 2011-2015. The overarching purpose of this plan is to reduce incidence, prolong survival and ensure the best quality of life possible for cancer patients.

Material to help you promote well being and prevention of illness can be obtained from the Health Promotion and Disease Prevention Directorate by calling on 23266000.

Healing & Disease Reversal The Series

by Albert Cilia-Vincenti

This series explores Dean Ornish's evidence-based claims of healing & disease reversal by dietary and lifestyle changes. He is a California University Professor of Medicine in San Francisco. This instalment introduces "good" and "bad" carbohydrates.

The body metabolises simple ("bad") and complex ("good") carbohydrates very differently. Although Dr Atkins and Professor Ornish agreed that too many people eat too many simple carbohydrates, they disagreed on the solution. Atkins advocated replacing simple carbohydrates with high-fat, high-protein foods, such as bacon, sausage, butter, steak, pork rinds and cheese. Telling people what they want to believe is partly the reason for the Atkins diet's popularity.

Dr Atkins was partly right in saying that too many "bad carbs", such as sugar, high-fructose corn syrup (sweetener used in the processed food industry), white flour and white rice may promote weight gain and chronic diseases. But his prescription was wrong. The solution is not to go from refined carbohydrates like white pasta to pork rinds, and from sugar to sausage, but to replace refined bad carbohydrates with unrefined good carbohydrates.

Good (unrefined, complex) carbohydrates include fruits, vegetables, whole grains, legumes, nuts and soy products in their natural unrefined forms. They are also high in fibre, which fills you up before you consume too many calories. Fibre also slows down digestion and intestinal absorption, helping to keep blood sugar within a normal range.

The "glycaemic index" is a measure of how much a given food will raise blood sugar, that is, how fast a carbohydrate in food is converted to glucose. Good carbohydrates have a low glycaemic index and bad carbohydrates have a high glycaemic index.

"Glycaemic load" takes into account both a typical serving size and how quickly the food is absorbed. This is probably a better indicator (than glycaemic index) of how foods will affect blood sugar.

A carrot, for example, has a high glycaemic index but a low glycaemic load, because its carbohydrates are absorbed rapidly but there aren't many of them. Glycaemic load is the amount of carbohydrate in a food serving multiplied by that food's glycaemic index. So although the glycaemic index of a carrot is about the same as that of a baked potato, the latter's glycaemic load is much higher because a potato is very dense in carbohydrates, whereas a serving of carrots doesn't contain many carbohydrates. **Eating a baked potato therefore causes a sharp rise in some people's blood glucose whereas a carrot does not.** This important distinction is not always clear to diabetics. The accompanying table illustrates this.

Food (serving size)	Carbohydrate Content (in grams)	Glycaemic Index (percent expressed as decimal)	Glycaemic Load (rounded to nearest tenth)
Potato (1 baked)	37	1.21	*45*
Carrots (½ cup cooked)	8	1.31	*10*
Lentils (½ cup cooked)	20	0.41	*8*
Dry beans (½ cup cooked)	27	0.60	*16*
White rice (½ cup cooked)	35	0.81	*28*
Wild rice (½ cup cooked)	18	0.78	*14*
White bread (2 slices)	24	1.00	*22*
Whole-grain bread (2 slices)	24	0.64	*15*
White pasta (1 cup cooked)	40	0.71	*28*
Whole-grain cereal (1 cup)	24	0.60	*14*
Cornflakes (1 cup)	26	1.19	*31*
Raisins (½ cup)	47	0.96	*45*
Corn chips (1 oz)	15	1.05	*16*
Popcorn (air-popped, 1 cup)	5	0.79	4

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Prescribing humour in Healthcare - Part I

by Joseph Agius

The most creative aspect of language is humour and it is one of the most important topics in the study of communication. The healing power of humour and laughter has been recorded and used throughout history. Humour is universal and there are claims of very beneficial effects from the use of positive feelings and emotions associated with laughter. Bertrand Russell notes that *"Laughter is the most inexpensive and most effective wonder drug. Laughter is a universal medicine".* During last October and November, I had the opportunity and pleasure to deliver an eight week course on **'Prescribing Humor in Health Care: And I ain't kiddin!'** to health professionals. The course was very well organized and coordinated by the Malta Institute of Medical Education (MIME). Eighteen participants took part in course and professionals included doctors, nurses, physiotherapists, radiographers, psychotherapists, occupational therapists and speech language pathologists among others.

My position in the field of health and humour

Virus is a Latin word used by doctors to mean 'your guess is as good as mine' Bob Hope (1903-2003)

Why did I start with a joke? When Professor Peter Serracino Inglott was arguing why a book that he published **'Peopled Silence'**[1] began with a joke, he stated:

"It's not this joke that was important, but a joke; any joke really would have done. It's simply that I think that jokes are the paradigmatic example of language. The playful use of language is the most illuminating of all its many and various uses, because the most singular aspect of language - namely its creativity - is most manifest in wit and humor - in jokes".

So, this is serious business. Another 'why' question. Why am I interested in this area? In anything one does, the passion is highly essential. I happen to be passionate both in my work as a speech language pathologist/ fluency specialist, and in my interest in comedy. It just happened that both fields crossed paths.

What inspired me to research on the relationship between humour and therapy? I was inspired by a client of mine, Simon (not the real name to protect anonymity), who was a lively young boy and who actively and joyfully participated in my group therapy sessions for school aged children who stutter. He was full of fun, wit, and always smiling - and he stuttered! He was an inspiration to his mates and also to speech pathology undergraduate students who were on observation placements in my clinic. They were impressed by his popularity and charm. Eight years later, now a young man aged 18 years, he was referred again for stuttering intervention. He presented as a serious young man, anxious, tense and without a smile. He claimed "I lost the young Simon". He had lost his zest for life, his wit and his excitement. If only our intervention could bring back the harmony, serenity and wit of the 'young Simon'.

This led me to study attitude changes towards communication when using creativity and humour during intervention. Findings from the study provided a framework for the 'Smart Intervention Strategy (SIS)' for school-age children who stutter. It includes components of creative expression through thinking skills and humour.

Humour and Health

Although humour seems to be an obviously important coping skill to get along our daily life, it has not always been considered important enough for researchers to study humour 'seriously'. It is only recently that psychologists and medical researchers began to systematically look at the ways in which humour contributes to physical and mental health.

However, we are often presented with media reports of scientific evidence claiming to demonstrate that humour and laughter are beneficial for various aspects of physical health. Martin[2] notes that over the past two decades, about 50 published articles have reported empirical investigations on the effects of humour and physical health. Such studies have investigated the effects of humour in various aspects of health such as immunity, pain tolerance, blood pressure, etc. The most consistent research support has been found for pain tolerance. There are several studies that report encouraging results, showing that after a laughter experience subjects are able to tolerate greater pain.

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Move over Dr Who....


Victor Grech painting

by Marika Azzopardi

There never seems to be a dull moment around Victor Grech ... Professor Victor Grech. This busy 45-year-old projects energy and alert enthusiasm even whilst maintaining a calm demeanour in the process of contemporarily answering my interview questions, replying to calls and painting a seascape. I sit back relaxed in my observations as I note down comments with one eye on the developing painting and another on the endless collection of shelved sci-fi books in Professor Grech's study.

First things first. Victor Grech is a paediatrician who, way back in 1994 decided to specialise in paediatric cardiology at the Great Ormond Hospital in London. His first doctorate tackled Congenital Heart Disease in Malta and was based on observations carried out back home. Married to a pharmacist and the father of two young children, means that, in his own words, "As a parent I understand children better, and arm myself with more patience when dealing with their own parents." That was his objective reply. When asked for a subjective one, he replied, "The scariest bit of being a paediatrician and a parent was waiting for my children to be born, knowing that there were a million things that could go wrong and praying none of them would touch our babies. Yes indeed, ignorance is bliss in this kind of situation and knowing all about what can possibly go wrong is definitely not always helpful."

As a general paediatrician Professor Grech's patients present with a wide range of medical problems but the most common problems he faces are minor infections namely caused by respiratory problems. However, he also added that notwithstanding the medical problems which he sees, the evolution of our social enmeshment means that, "A new phenomenon that we are facing is that involving children who develop psychological problems during or after their parents' separation. There is really a great deal of trauma out there."

On the other hand, as a paediatric cardiologist his patients range from newborns to 60-year-olds who had their first heart surgery done when they were babies and who, today, require attention at the Grown-Up Congenital Heart Disease clinic. He holds this clinic once a month in conjunction with an adult cardiologist. Where infants and children are involved, he carries out interventional cardiology which allows him to enter the body through the groin from where he can introduce instruments to treat relatively simple cardiac problems such as narrow or leaking valves, and holes in the heart. This also means that he is the only Maltese paediatrician who carries out such surgical interventions.

Incidentally Professor Victor Grech is also the most published doctor in Malta. Apart from publishing on paediatric cardiology and general paediatrics, he also lectures on both topics at the University of Malta. Recently he brushed shoulders with a totally different department at the University of Malta – the Faculty of Arts, and this is where his passion for science fiction comes in. "I have been an avid sci-fi reader since the age of seven when I read a juvenile sci-fi author called Hugh Walters. I have been hooked ever since, and today I really cannot tell you how many sci-fi books I have read so far – definitely thousands. I have a collection of some 1500 books here, not to mention the

collection of *Analog* magazine. I've read most of that, and I have practically the whole collection from 1938 to present day, which I have accumulated over the years in a staggered fashion."

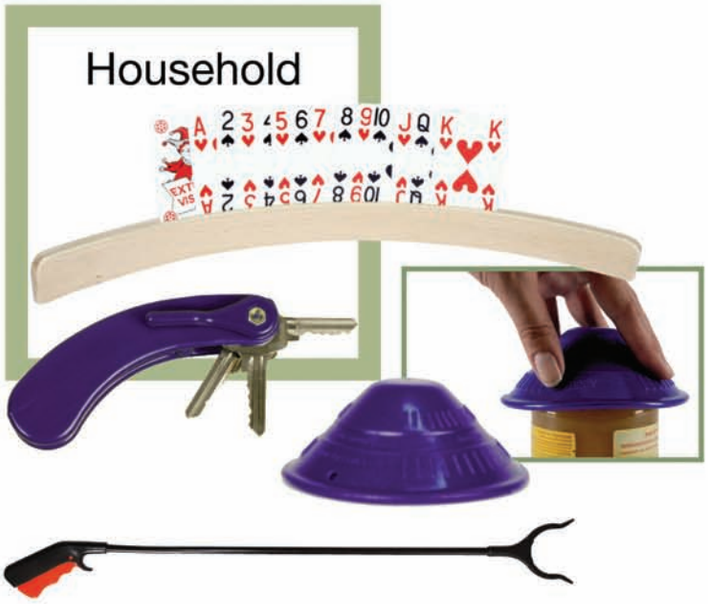
Professor Grech tells me that today his favourite sci-fi author is Robert Heinlein whose personal philosophy has particularly inspired him as a man of science. He has also been inspired by the likes of John Varley as well as by John Campbell who is considered to have been instrumental in changing the face of science fiction literature. "Before Campbell, science fiction was essentially pulp fiction, and the front covers of

Purple and violet

On the beach

older sci-fi literature are all about weirdly shaped and eccentric monsters attacking terrified humans. Today sci-fi is more complex and vast, verging of some absolutely unexpected issues, as well as some rather terrifying diversities that are slowly creeping in to taint people's visual image of sexuality." One of the aspects that particularly inspire Professor Grech is the issue of infertility and sterility as tackled in sci-fi literature. He explains that this led him to approach the Faculty of Arts proposing a thesis on 'Infertility in Science Fiction'. An advanced draft of this has been very recently completed, and passed on to his supervisors Claire Thake and Ivan Callus.

And then comes the art. "When I turned 40, like most other adults, I had my very own mid-life crisis to deal with and somehow this spurred me on to start painting. I have been painting regularly and earnestly ever since, thanks to the great inspiration and unofficial teaching provided by the Impressionist John Borg Manduca from whom I have learnt how to paint in oils with the help of a palette knife. I love doing seascapes mostly, and I find it relaxes me somewhat. It is my own way of switching off." As I take leave of Professor Grech, I wonder how many of his junior patients know about his intriguing interest in science fiction and his artistic streak. As I exit Pembroke, a strangely vivid image of Goldrake and Mazinga Z flying through a Monet-like seascape accompanies me home….



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Uncommon Inflammatory Breast Diseases that Mimic Cancer. Part II

by Pierre Vassallo

Inflammatory breast lesions have radiologic features that often mimic those of malignancy. Infective mastitis is the most common condition that may be indistinguishable clinically from carcinomatous mastitis.

In the last article, we discussed inflammatory conditions caused by immunological mechanisms including Chug Strauss, Amyloidosis, Wegener's Granulomatosis, Sarcoidosis and Diabetic Mastopathy.

The present article will present three categories of inflammatory disease of the breast: those caused by atypical infections, vascular disease and a further group in which the cause is unknown (pathogenetically unclassified). These less common forms of inflammatory breast disease constitute an even greater diagnostic dilemma and always require biopsy.

Specific Infections

Mycobacterial, fungal, and parasitic infections, although rare, can induce an inflammatory, commonly granulomatous reaction in the breast.

Among parasitic infections, filariasis has been described as presenting with a mass containing serpiginous calcifications, schistosomiasis as calcifications with mild architectural distortion, sparganosis as a lobulated mass with irregular contours, and echinococcosis as a dense, well-circumscribed mass at mammography with a heterogeneous, complex cystic appearance at US.

Among fungal infections, actinomycosis has been described as a lobulated mass with irregular borders with skin thickening. Blastomycosis manifests as a partially circumscribed subcutaneous mass or bilateral masses with well-defined contours at mammography and a complex cystic structure on ultrasound.

Mycobacterium tuberculosis infections are a serious clinical problem in undeveloped countries. Although uncommon in Western countries due to socioeconomic and medical progress, an increase in disease prevalence was observed in the early 90's in immune-compromised patients particularly those infected with human immunodeficiency virus.

Tuberculous mastitis is secondary in most patients, but the primary focus may remain clinically occult. The infection may reach the breast through retrograde spread from axillary, cervical or internal mammary nodes, direct extension from contiguous structures such as the chest wall or haematogenous dissemination. The latter has been observed in acquired immunodeficiency syndrome patients with miliary breast involvement. Entry through the nipple may account for some pregnancy-related infections.

Clinically, most patients present with a hard, painless lump in the breast that is indistinguishable from cancer. Up to 50% of patients have axillary node enlargement. Premenopausal women are more often affected, and there may be a predilection for women who are lactating.

The radiologic manifestations of mammary tuberculosis can be classified into three distinct patterns: nodular, diffuse, and sclerosing. The nodular pattern manifests as an ill-defined or irregular mass that closely resembles carcinoma (Figure 1).

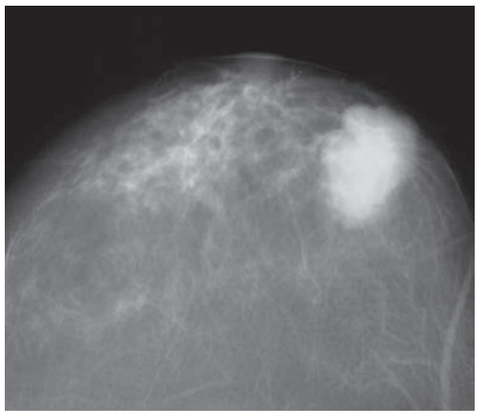


Figure1: Nodular type breast tuberculosis in a patient with a previous history of pulmonary TB. Histological analysis showed extensive granulomatous inflammation with epithelioid and Langhans giant cells.

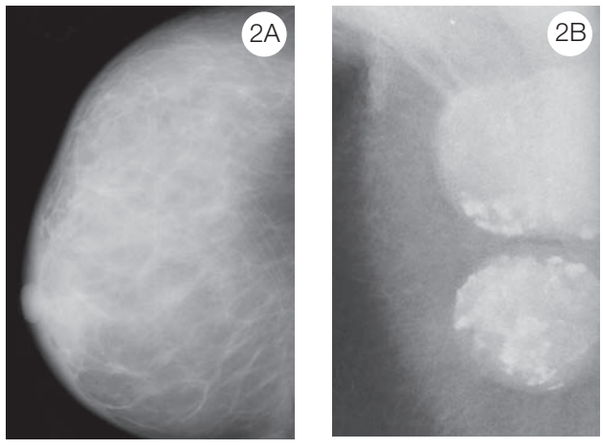
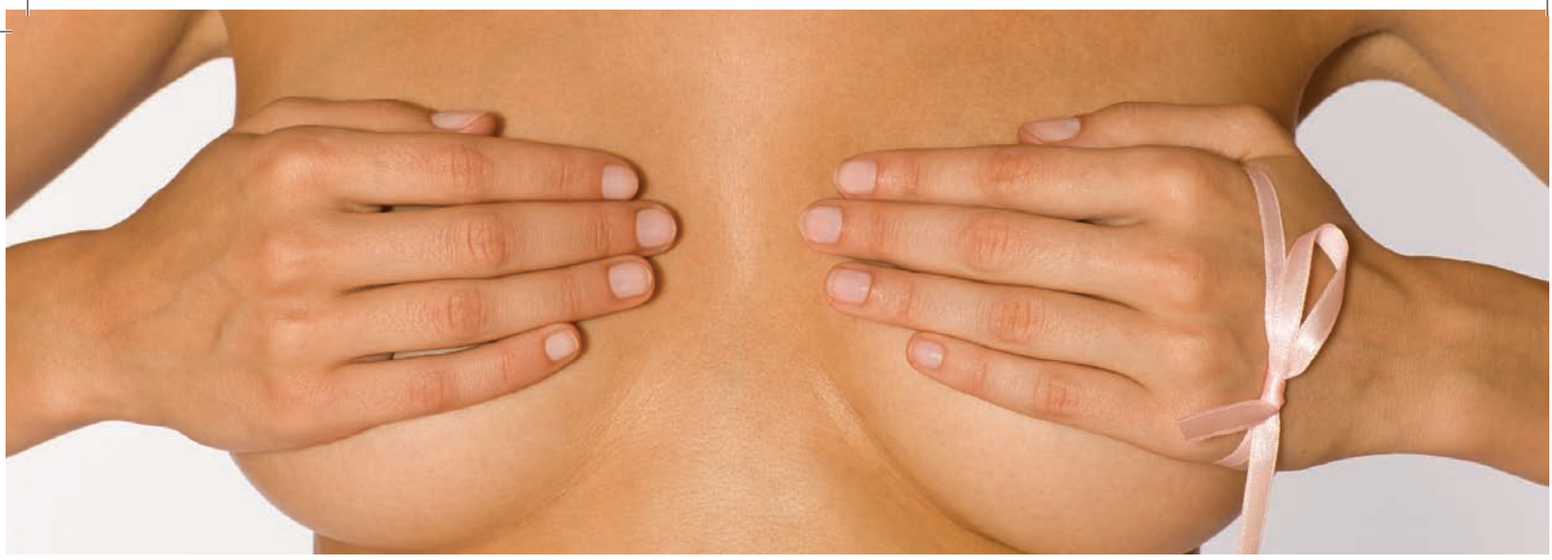


Figure2: (a) Diffuse type breast tuberculosis present as diffuse density due to lymphatic infiltration with thickening of the Cooper ligaments. (b) Axillary calcified nodes are present.



The diffuse pattern simulates inflammatory carcinoma with skin thickening (Figure 2a). The sclerosing type, which usually affects elderly women, manifests as increased breast density with areas of architectural distortion (Figure 3). Large, dense, calcified axillary nodes can be demonstrated with appropriate axillary views and are considered to be suggestive of the disease (Figure 2b). US can be useful in the evaluation of the internal cystic, solid, or complex structure of the masses and can help identify a fistula or sinus tract. Contiguous chest wall and lung involvement are best evaluated by CT imaging.

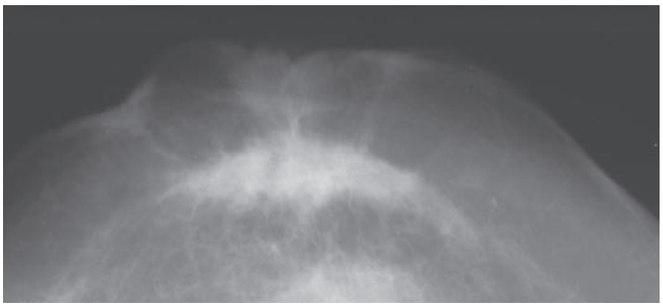


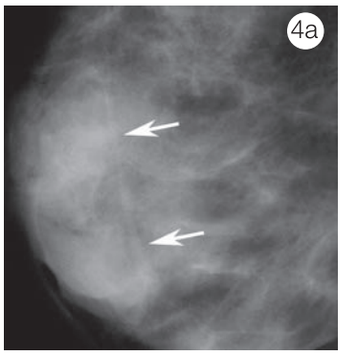
Figure 3: Sclerosing type breast tuberculosis presenting with a central spiculated mass with architectural distortion causing nipple and skin retraction.

The diagnostic confirmation of mammary tuberculosis is often difficult and is usually based on inflammatory and granulomatous findings at FNA cytological analysis or biopsy. Acid-fast bacteria are usually not detected and cultures develop slowly and are not always demonstrative.

Vascular Disorders (Mondor Disease)

Mondor disease is a rare, usually self-limited thrombophlebitis of the subcutaneous veins of the breast. It has commonly been related to trauma, physical exertion, and surgery, and may be associated with carcinoma. About 25% of cases involve men.

Diagnosis is usually established clinically on the basis of the presence of a characteristic painful, tender, palpable cord-like structure, generally located on the lateral aspect of the breast. At mammography, the thrombosed vein may appear as a cord-like structure (Figure 4a). Rarely, the vein calcifies. At US, the vein appears as a superficial tubular structure filled with low-level internal echoes due to thrombus (Figure 4b).



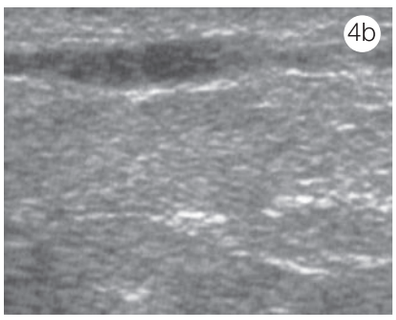


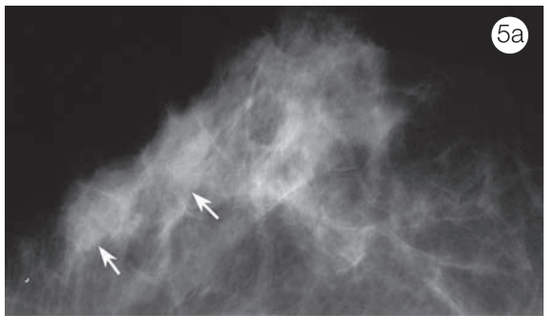
Figure 4:(a) Mondor disease presenting as a superficial linear density (arrows) on mammography with a corresponding to the cord-like area seen at clinical examination. (b) Ultrasound image reveals the thrombophlebitic vein.

Granulomatous Mastitis

Granulomatous mastitis is a very rare inflammatory disease of unknown origin. Immunologic causes have been postulated, but the absence of vasculitis or of a prominent lymphocytic component is against this hypothesis.

The diagnosis of granulomatous mastitis is based on exclusion, since it depends on the demonstration of a particular histological pattern combined with the exclusion of other granulomatous reactions presenting in this and the previous article. At pathologic analysis, granulomatous mastitis manifests as a non-caseating, non-vasculitic granulomatous inflammatory reaction centered on lobules. Fat necrosis, abscess formation, and fibrosis may occur.

Clinically, granulomatous mastitis generally manifests as a distinct, firm to hard mass that may involve any part of the breast but tends to spare the subareolar regions. An association with pregnancy or lactation has been documented, as this disease typically affects younger women, usually within 6 years of pregnancy.



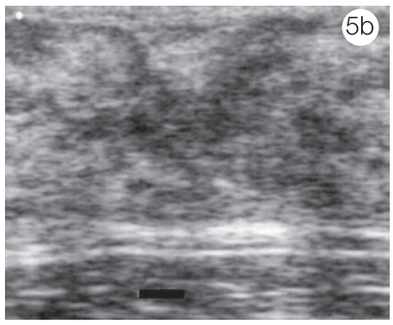


Figure5: (a) Granulomatous mastitis 2 years after pregnancy presents with subtle asymmetric density on mammography (arrows) at the location of the palpable mass. (b) Ultrasound image reveals a heterogeneously hypoechoic tubular mass with ill-defined margins surrounded by hyperechoic boundaries.

The mammographic features are variable, ranging from no findings in patients with dense breasts to a mass lesion and focal asymmetric density. The US appearance of multiple clustered contiguous hypoechoic tubular lesions has been considered suggestive of the disease, although the latter feature is not always found (Figure 5).
The prognosis of this condition is good, although local recurrence has been reported. Primary treatment consists of excision biopsy. Corticosteroid therapy has also proved effective.

In summary, diagnosis of the above inflammatory conditions of the breast is complex and requires full knowledge of previous history, detailed imaging studies and almost always biopsy.

Mental Health Association Malta

Mental Health Association Malta (MHAM) is a registered non-profit making organisation representing the families and carers of people with mental illness. It promotes the interests and well-being of all people affected by severe mental illness including their families and carers. MHAM believes that carers must be acknowledged as partners in care supporting the person with mental illness.
MHAM was founded in 1998 but the “seed” was sown in 1982 by Professor Abraham Galea together with staff at Mount Carmel Hospital and families of people affected by mental illness. The MHAM is affiliated with European Federation of Associations of Families of people with Mental Illness (EUFAMI) and one of its members is currently the vice-president of EUFAMI.
Our mission is to remove the stigma surrounding mental illness, educate to counteract ignorance and misinformation, advocate for the improvement of health and social care of people with mental illness and their carers, and support family carers in their needs.
An annual empowerment course consisting of 13 sessions is being organized in an attempt to help participants understand mental illness and work on strategies (problem-solving and communication skills) that help the affected person recover a better quality of life. Various professionals working with the mentally ill are participating. The course is intended for family members, carers, those working or planning to work in the mental health sector, NGOs, psychiatric nurses, social workers community workers and educators

Further information on the Mental Health Association Malta can be requested by contacting assistance@mhamalta.com or 21378469 / 79093873.

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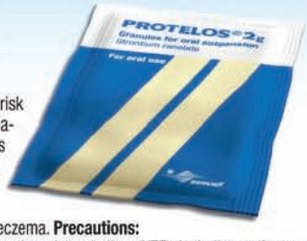

Presentation and Composition: Each sachet contains 2 g of strontium ranelate. **Indication:** Treatment of postmenopausal osteoporosis to reduce the risk of vertebral and hip fractures. **Dosage:** One sachet daily at bedtime diluted in a glass of water. **Properties:** Antiosteoporotic agent which both increases bone formation and reduces bone resorption, resulting in a rebalance of bone turnover in favor of bone formation. Protelos significantly reduces the risk of vertebral fractures in postmenopausal osteoporotic women with or without previous fractures, and also significantly reduces the risk of hip fractures. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Interactions:** Should be taken 2 hours apart from food, milk and derivative products, and medicinal products containing calcium. Should be taken 2 hours before antacids. Treatment should be suspended while taking oral tetracycline and quinolone antibiotics. **Side effects:** Common: Nausea, diarrhea, loose stools, headache, dermatitis, eczema. **Precautions:** Not recommended in patients with a creatinine clearance below 30 mL/min due to lack of data. Use with caution in patients at increased risk of venous thromboembolism (VTE), including patients with a past history of VTE. Use inductively coupled plasma atomic emission spectrometry or atomic absorption spectrometry methods to assess blood and urinary calcium concentrations, as strontium interferes with colorimetric methods. In case of hypersensitivity-induced cutaneous manifestation, therapy should be stopped immediately and not re-started. Use with caution in patients with phenylketonuria, as Protelos contains phenylalanine. *Please refer to the complete summary of product characteristics for your country as variations may exist.* **LES LABORATOIRES SERVIER** France. Correspondent: **SERVIER INTERNATIONAL**: 22, rue Garnier - 92578 Neuilly-sur-Seine - France.

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References: 1. Marie PJ, Ammann P, Boivin G, et al. *Calcif Tissue Int.* 2001;69:121-129. 2. European Summary of Product Characteristics.
3. Meunier PJ, Roux C, Seeman E, et al. *N Engl J Med.* 2004;350:459-468. 4. Rizzoli R, Reginster JY Diaz-Curiel M, et al. *Osteoporos Int.* 2004;15:S18. Abstract OC39.

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