ROSEMONTPHARMA.COM WINS TOP WEBSITE AWARD

Rosemont's recently updated, new-look website has been given an "Outstanding Achievement" award in the Pharmaceutical category by the Interactive Media Council (IMC).

The IMC is an organization of leading web designers, developers, programmers, advertisers and other web-related professionals whose dedicated aim is to "increase the standards of excellence on the Internet".

Gaining the award means that Rosemont can now include the coveted IMA digital award icon on the website – indicating the degree of excellence the site has achieved.

According to the IMC: "The Outstanding Achievement award is an extremely challenging award to win. The Rosemont website has excelled in all areas of our judging criteria and represents a very high standard of planning, execution and overall professionalism."

Visit: **www.rosemontpharma.com**

Abbreviated Prescribing Information: Warfarin Sodium 1mg/1ml Oral Suspension. Consult Summary of Product Characteristics before prescribing. Presentation: A white to off white suspension, each 1ml of suspension contains Warfarin Sodium 1mg. **Therapeutic Indications:** Prophylaxis of systemic embolism in patients with rheumatic heart disease and atrial fibrillation. Prophylaxis after insertion of prosthetic heart valves. Prophylaxis of venous thrombosis and pulmonary embolism and for use in the treatment of these conditions to prevent their extension. **Posology:** Adults: Between 3mg and 10mg per day. **Contra-indications:** Known hypersensitivity to warfarin or to any of the ingredients contained in warfarin suspension. Haemorrhagic stroke. Clinically significant bleeding. Use within 72 hours of surgery with risk of severe bleeding. Use within 48 hours postpartum. Warfarin is contraindicated in pregnancy. Drugs where interactions lead to a significantly increased risk of bleeding. Anticoagulation is contraindicated in any physical condition in which the risk of haemorrhage might be greater than the potential clinical benefits of anticoagulation **Precautions:** Most adverse events reported with warfarin are a result of over anticoagulation. If this preparation replaces or is replaced by another warfarin product, the patient should be monitored closely in the period immediately following the change. *Thrombophilia:* Patients with protein C or S deficiency are at risk of developing skin necrosis when starting warfarin treatment. Haemorrhage can indicate an overdose of warfarin has been taken. Warfarin treatment should be re-started 2–14 days following ischaemic stroke, depending on the size of the infarct and blood pressure. Minor surgical procedures with low risk of bleeding can be performed in general with an INR of <2.5. Where there is a risk of severe bleeding, warfarin should be stopped 3-5 days prior to surgery. Where it is necessary to continue anticoagulation the INR should be reduced to <2.5 and heparin therapy should be started. If surgery is required and warfarin cannot be stopped 3 days beforehand, anticoagulation should be reversed with low-dose vitamin K. The timing for re-instating warfarin therapy depends on the risk of post-operative haemorrhage. In most instances warfarin treatment can be re-started as soon as the patient has an oral intake. In most cases warfarin need not be stopped before routine dental surgery. Due to a high risk of bleeding, patients with history of peptic ulcers be reviewed regularly. Many drugs and foods interact with warfarin and affect the prothrombin time. Any change to medication, including self-medication with OTC products, warrants increased monitoring of the INR. The rate of warfarin metabolism depends on thyroid status; patients with hyper- or hypo-thyroidism should be closely monitored on starting warfarin therapy. The following may exaggerate the effect of warfarin, and necessitate a reduction of dosage: loss of weight, acute illness, cessation of smoking. The following may reduce the effect of warfarin, and require the dosage to be increased: weight gain, diarrhoea, vomiting. Acquired or inherited warfarin resistance should be suspected if larger than usual daily doses of warfarin are required to achieve the desired anticoagulant effect. *Excipient warnings:* The product contains liquid maltitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine. **Interactions:** Warfarin has a narrow therapeutic range and the product information for any new concomitant therapy should be consulted for specific guidance on warfarin dose adjustment and therapeutic monitoring. Concomitant use of drugs used in the treatment or prophylaxis of thrombosis, or other drugs with adverse effects on haemostasis may increase the pharmacological effect of warfarin, increasing the risk of bleeding. Fibrinolytic drugs such as streptokinase and alteplase are contraindicated in patients receiving warfarin Drugs which should be avoided if possible: Clopidogrel, NSAIDs, Sulfinpyrazone, Thrombin inhibitors such as bivalirudin, dabigatran, ipyridamole, unfractionated heparins and heparin derivatives, low molecular weight heparins, fondaparinux, rivaroxaban, glycoprotein IIb/IIIa receptor antagonists such as eptifibatide, trofiban and abciximab Prostacyclin, SSRI and SNRI antidepressants, other drugs which inhibit haemostasis, clotting or platelet. Low-dose aspirin with warfarin may increase the risk of gastrointestinal bleeding. **Drug interactions:** allopurinol, capecitabine, erlotinib, disulfiram, azole antifungals, omeprazole, paracetamol (prolonged regular use), propafenone, amiodarone, tamoxifen, methylphenidate, chloral hydrate, chloramphenicol, cimetidine, danazol, dextropropoxyphene, glibenclamide, phenylbutazone, quinidine, stanozolol, thyroxine, triclofos zafirlukast, fibrates, statins (not pravastatin; predominantly associated with fluvastatin) erythromycin, sulfamethoxazole, metronidazole, barbiturates, primidone, carbamazepine, griseofulvin, oral contraceptives, rifampicin, azathioprine, phenytoin, aminoglutethimide, phenazone, corticosteroids, nevirapine, ritonavir, broad spectrum antibiotics, colestyramine and sucralfate glucosamine. **Interactions with herbal products:** St John's Wort. **Alcohol:** Acute ingestion of a large amount of alcohol may inhibit the metabolism of warfarin and increase INR. Conversely, chronic heavy alcohol intake may induce the metabolism of warfarin. **Interactions with food and food supplements:** cranberry juice, grapefruit juice, liver, broccoli, Brussels sprouts and green leafy vegetables. Patients should be informed of the need to seek medical advice before undertaking any major changes in diet. **Laboratory tests:** Heparins and danaparoid may prolong the prothrombin time, therefore a sufficient time interval should be allowed after administration before performing the test. **Pregnancy and lactation:** Contraindicated; women of child-bearing age should use effective contraception during treatment. At therapeutic dosages warfarin can be used during breast-feeding. **Effects on ability to drive and use machines:** No specific effect. **Undesirable effects:** Fever, hypersensitivity, cerebral haemorrhage; cerebral subdural haematoma, haemorrhage, haemothorax, epistaxis, gastrointestinal haemorrhage; rectal haemorrhage; haematemesis; pancreatitis; diarrhoea; nausea; vomiting; melaena, rash; alopecia; purpura; erythematous swollen skin patches leading to ecchymosis, infarction and skin necrosis, jaundice; hepatic dysfunction, haematuria, unexplained drop in haematocrit; haemoglobin decreased, purple toes. **Overdose:** The benefit of gastric decontamination is uncertain. If the patient presents within 1 hour of ingestion of more than 0.25 mg/kg or more than the patient's therapeutic dose, consider activated charcoal. In cases of: *life-threatening haemorrhage; non-life threatening haemorrhage; patients on long-term warfarin therapy without major haemorrhage and patients NOT on long-term anticoagulants without major haemorrhage* please refer to the product SPC. The degree of reversal of anticoagulation must be decided on an individual basis. Full reversal with vitamin K may result in prolonged resistance to warfarin, giving rise to the possibility of valve thrombosis and thrombo-embolism in patients with prosthetic heart valves **Shelf Life and Storage:** 18 months (1 month after opening). Do not store above 25°C. **Legal Category:** POM. **Pack Size and NHS Price:** 150ml - £90.00. **Marketing Authorisation Holder:** Rosemont Pharmaceuticals Ltd, Rosemont House, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE. **Date of Preparation:** October 2010.

Abbreviated Prescribing Information: ALENDRONIC ACID 70mg/100ml Oral Solution. Consult Summary of Product Characteristics before prescribing. Presentation: Orange coloured opalescent solution containing 70mg alendronic acid (as 91.35mg sodium alendronate trihydrate) in each 100ml bottle. **Therapeutic Indications:** Treatment of post-menopausal osteoporosis. Alendronic acid reduces the risk of vertebral and hip fractures. **Posology:** For oral administration. *Adults and Elderly:* One 70mg unit-dose (100 ml) once weekly. It must be taken at least 30 minutes before the first food, beverage, or medicinal product of the day followed by at least 30ml of plain water only. Patients should not lie down for 30 minutes after taking Alendronic acid and should not take at bedtime or before arising for the day. Patients should receive supplemental calcium and vitamin D if dietary intake is inadequate. *Use in renal impairment:* No dosage adjustment is necessary in patients with a glomerular filtration rate (GFR) greater than 35 ml/min. Alendronic acid is not recommended for patients with impaired renal function where GFR is less than 35 ml/min. *Use in children:* There is insufficient data to support its use in children. **Contra-indications:** Abnormalities of the oesophagus and other factors which delay oesophageal emptying such as stricture or achalasia, inability to stand or sit upright for at least 30 minutes, hypersensitivity to alendronic acid or to any of the excipients, hypocalcaemia, patients who have difficulty swallowing liquids, patients at risk of aspiration. **Precautions:** Alendronic Acid can cause local irritation of the upper gastro-intestinal mucosa. Because there is a potential for worsening of the underlying disease, caution should be used when Alendronic Acid is given to patients with active upper gastro-intestinal problems, such as dysphagia, oesophageal disease, gastritis, duodenitis, ulcers, or with a recent history (within the previous year) of major gastro-intestinal disease. In patients with known Barrett's oesophagus, the benefits and potential risks should be considered on an individual patient basis. Oesophageal reactions have been reported in patients receiving alendronic acid. Patients should be instructed to discontinue alendronic acid and seek medical attention if they develop symptoms of oesophageal irritation such as dysphagia, pain on swallowing or retrosternal pain, new or worsening heartburn. There have been rare reports of gastric and duodenal ulcers, some severe and with complications. Osteonecrosis of the jaw, generally associated with tooth extraction and/or local infection, has been reported in patients with cancer receiving treatment regimens including primarily intravenously administered bisphosphonates. Many of these patients were also receiving chemotherapy and corticosteroids. Osteonecrosis of the jaw has also been reported in patients with osteoporosis receiving oral bisphosphonates. A dental examination with appropriate preventive dentistry should be considered prior to treatment with bisphosphonates in patients with concomitant risk factors. While on treatment, these patients should avoid invasive dental procedures if possible. Clinical judgement of the treating physician should guide the management plan of each patient based on individual benefit/risk assessment. Bone, joint, and/or muscle pain has been reported in patients taking bisphosphonates. Stress fractures of the proximal femoral shaft have been reported in patients treated long-term with alendronic acid. Poor healing of these fractures was also reported. Discontinuation of bisphosphonate therapy in patients with stress fracture is advisable pending evaluation of the patient, based on individual benefit risk assessment. Patients should be instructed that if they miss a dose of *Alendronic Acid 70 mg Oral Solution*, they should take one single unit-dose (100 ml) on the morning after they remember. They should not take doses on the same day but should return to taking one unit-dose once a week, as originally scheduled on their chosen day. Hypocalcaemia must be corrected before initiating therapy with alendronic acid. Other disorders affecting mineral metabolism should also be effectively treated. In patients with these conditions, serum calcium and symptoms of hypocalcaemia should be monitored during therapy. There have been rare reports of symptomatic hypocalcaemia, which have occasionally been severe and often occurred in patients with predisposing conditions. Ensuring adequate calcium and vitamin D intake is particularly important in patients receiving glucocorticoids. This medicinal product contains 0.15 % volume ethanol. Harmful for those suffering from alcoholism. To be taken into account in high-risk groups such as patients with liver disease, or epilepsy. *Excipient warnings:* contains sunset yellow (E110) methyl and propyl parahydroxybenzoates (E218, E216) that may cause allergic reactions. **Interactions:** Patients must wait at least 30 minutes after taking alendronic acid before taking any other oral medicinal product. No other interactions with medicinal products of clinical significance are anticipated. Since NSAID use is associated with gastrointestinal irritation, caution should be used during concomitant use with alendronate. In clinical studies alendronic acid was used concomitantly with a wide range of commonly prescribed medicinal products without evidence of clinical adverse interactions. **Pregnancy and Lactation:** Alendronic acid should not be used during pregnancy. It is not known whether alendronate is excreted into human breast milk so alendronic acid should not be used by breast-feeding women. **Effects on Ability to Drive and Use Machines:** Certain adverse reactions that have been reported with alendronic acid may affect some patients' ability to drive or operate machinery. **Undesirable Effects:** Hypersensitivity reactions, symptomatic hypocalcaemia, headache, dysgeusia, uveitis, scleritis, episcleritis, abdominal pain, dyspepsia, constipation, diarrhoea, flatulence, oesophageal ulcer, dysphagia, abdominal distension, acid regurgitation, nausea, vomiting, gastritis, oesophagitis, oesophageal erosions, melena, oesophageal stricture, oropharyngeal ulceration, upper gastrointestinal PUBs (perforation, ulcers, bleeding,) rash, pruritus, erythema, alopecia, rash with photosensitivity, severe skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis, musculoskeletal pain, osteonecrosis of the jaw has been reported, transient symptoms as in an acute-phase response (myalgia, malaise and rarely, fever), typically in association with initiation of treatment, dizziness, vertigo, joint swelling, stress fractures, asthenia, peripheral oedema, asymptomatic, mild and transient decreases in serum calcium and phosphate. **Overdose:** No specific information is available on the treatment of overdosage with alendronic acid. Milk or antacids should be given to bind alendronic acid. Owing to the risk of oesophageal irritation, vomiting should not be induced and the patient should remain fully upright. **Shelf Life and Storage:** 2 years, store below 25°C. **Legal Category:** POM. **Pack size and Price:** 4x100mls - £22.80. **Marketing Authorisation Holder:** Xeolas Pharmaceuticals Ltd., 97 Furry Park Road, Dublin 5, Ireland. **Date of Preparation:** November 2010. Further information is available on request from Rosemont Pharmaceuticals Ltd., Rosemont Pharmaceuticals Ltd., Rosemont House, Yorkdale Industrial Park, Braithwaite Street, Leeds LS11 9XE on Tel 0113 244 1999.

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Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk Adverse events should also be reported to Rosemont Pharmaceuticals Ltd on

SPECIAL REQUEST

ISSUE 10

ROSEMONT LAUNCHES FIRST LICENSED LIQUID WARFARIN

Rosemont Pharmaceuticals has recently introduced the first licensed oral liquid warfarin. Previously, liquid warfarin was only available as a 'Special', but now a Marketing Authorisation has been granted to Rosemont, making this the first and only licensed oral liquid warfarin in the UK. Rosemont's 150ml Warfarin Sodium 1mg/1ml, oral anticoagulant is sucrose, ethanol, lactose and gluten free with an 18-month shelf life.

Says Jan Flynn, Marketing Manager at Rosemont Pharmaceuticals: "Warfarin is a potent drug with a narrow therapeutic range and patients frequently need to adjust their dose of warfarin, depending on the results of regular INR (international normalised ratio) tests. Liquid warfarin is supplied with an oral syringe and 1mg equates to 1ml of liquid making dose adjustment easier. Patients who have trouble swallowing tablets may be instructed by a healthcare provider to crush and/or dissolve them in water. This action may result in inaccurate dosing as tablets may not fully dissolve so they don't take the full dose. Also the potency of the product may change by doing this as maintaining the correct pH is vital. New Licensed Liquid Warfarin can provide more accurate dosing.

Warfarin is one of the 50 most prescribed drugs for the elderly[1] and research suggests that almost 60% of patients over 65 experience some difficulty swallowing solid medications[2]. Also, in older patients, pharmacodynamic changes can lead to an increase in response to warfarin. Crushing or dissolving warfarin tablets which have such a narrow therapeutic range, to make them easier to take could reduce efficacy and/or cause side effects. This is because warfarin is a highly potent drug and any slight variation in dosing means the patient may not be receiving the exact same dose every time, potentially leading to serious negative clinical outcomes.

There is a real therapeutic need for a licensed oral liquid warfarin, which has now been fulfilled by Rosemont."

References:
1. Oral Liquid Formulary – guidance for healthcare professionals. D. Wright, 2006
2. Strachan I, Greener M. Medication-related swallowing difficulties may be more common than we realise. Pharmacy in Practice 2005; **15**: 411-14

WARFARIN THERAPY

Warfarin is used to treat and prevent the following conditions:

- Deep vein thrombosis - Each year, one in every 1,000 people in the UK is affected by DVT.
- Pulmonary embolism - around one in 10 people with untreated DVT will develop a pulmonary embolism.
- Transient ischaemic attacks (TIAs) – it is difficult to know how common TIAs are, but without treatment, there is a one in five chance of a person having a full stroke within four weeks of having a TIA.
- Stroke - approximately 11% of all deaths in the UK are caused by strokes. People who are over 65 years of age are most at risk from having strokes, although 25% of strokes occur in people who are under 65 years of age.
- Heart attack - each year in England, an estimated 111,000 people have a heart attack. Men are two to three times more likely to have a heart attack than women. Over the last decade, death rates from heart attacks in England have fallen by around 25%.

Source: NHS Choices, http://www.nhs.uk/conditions/anticoagulants-warfarin-/pages/introduction.aspx accessed 2nd November 2010

FIRST LICENSED LIQUID ALENDRONIC ACID COULD IMPROVE COMPLIANCE WITH OSTEOPOROSIS THERAPY

Rosemont Pharmaceuticals has recently announced the launch of new Alendronic Acid 70mg Oral Solution, a liquid bisphosphonate presented as a month's supply of 4 x 100ml single use doses for once weekly treatment of post-menopausal osteoporosis. This unique patented formulation is likely to benefit women who are unable or unwilling to take tablets and in particular those who are concerned about a tablet becoming stuck in their oesophagus.

Bisphosphonate tablets need to be swallowed whole. The acidic nature of the product means that if the tablet gets stuck or sits in place in the GI track, there is a risk of damage to the mucosa. Many patients suffer GI problems caused by the tablets which may lead them to discontinue treatment. Chewing or allowing the tablet to dissolve in the mouth can lead to oropharyngeal ulceration. If tablets are crushed and taken with food or drink, absorption is significantly impaired potentially leading to treatment failure.

Rosemont Pharmaceuticals' Alendronic Acid Oral Solution is the first oral liquid formulation of any bisphosphonate to be approved in the UK. The orange fruit drink appearance reinforces the pre-breakfast aspect of the product, which makes it easier to remember to take first thing in the morning as well as making it more appealing for patients. New research indicates that an increasing number of women discontinue therapy with bisphosphonate tablets due to a 'feeling of dread before needing to take their medication'[1]. The introduction of a liquid, patented formulation of a leading osteoporosis treatment is likely to help improve compliance, which could lead to fewer osteoporotic fractures.

Around 3 million people in the UK have osteoporosis[2] and treatment with a bisphosphonate is recommended first line by NICE, but compliance with bisphosphonate tablets is a major problem with 50% of patients discontinuing treatment within six months[3]. This non-compliance is linked to a 45% increased risk of fractures[4].

References:
1. Clark E et al. Why older women from primary care stop their bone protective therapy, Osteoporos Int (2010) **21** (Suppl 3) S 459-460
2. National Osteoporosis Society: http://www.nos.org.uk/NetCommunity/Page.aspx?pid=328&srcid=312 accessed 26th October 2010
3. Li et al. Non-persistence to anti-osteoporosis medications in the UK using the General Practice Research Database (GPRD) Rheumatology (2010) **49** (suppl 1):i23-i25
4. Penning-van Beest et al. Loss of treatment benefit due to low compliance with bisphosphonate therapy. Osteoporosis international (2008) vol 19 (4) pp 511-7

OSTEOPOROSIS – THE FACTS

- On the basis of current trends, hip fracture rates in the UK may increase from approximately 46,000 in 1985 to 117,000 in 2016
- Drug treatments have been shown to reduce the risk of fractures by up to 50%
- The total number of women prescribed medication for osteoporosis in the UK is approximately 480,000
- The cost of treating all osteoporotic fractures in post-menopausal women has been predicted to increase to more than £2.1 billion by 2020

Source: National Osteoporosis Society Fact Sheet 2006

SPLITTING TABLETS 'MAY MEAN PATIENTS TAKE WRONG DOSES'

Splitting pills could lead to patients taking the wrong doses, according to a new study published in the Journal of Advanced Nursing. Researchers from Ghent University in Belgium said there could be "serious clinical consequences" for patients and "tablets which have a narrow margin between a dose that is therapeutic and one that is toxic are riskiest." They found that 31% of the tablets that were split were different from the expected dose.

Dr Charlotte Verrue, who led the study, said there were many reasons for tablets to be divided. "It is done for a number of reasons: to increase dose flexibility, to make tablets easier to swallow and to save money for both patients and healthcare providers. However, the split tablets are often unequal sizes and a substantial amount of the tablet can be lost during splitting."

She said that most tablets were not suitable for splitting and it would be better for more doses to be available. "We would also like to see manufacturers introduce a wider range of tablet doses or liquid formulations so that tablet splitting becomes increasingly unnecessary."

Reference
Tablet-splitting: a common yet not so innocent practice. Verrue et al. Journal of Advanced Nursing. 67.1, pp 26-32. (January 2011). DOI: 10.1111/j.1365-2648.2010.05477

ADVICE FROM THE PDA

It has been reported that the Pharmacists' Defence Association (PDA) has received a number of enquiries regarding the dispensing of tablets/capsules where these are to be administered via crushing, dispersing or otherwise interfering with the integrity of the dosage unit. When approaching this issue the PDA "strongly advises" its members that although:

"There will be times where pharmacists acting in their patients best interests, may need to consider supplying a medicine in a manner or form which interferes with the integrity of its license; such decisions should only be taken after following a considered professional cognitive process. In so doing and despite going through such a process, the pharmacist will be taking a personal risk and in the event that something goes wrong, they will be held to account for their actions."

It is generally advised that a pharmacist **always** confirms that the drug is licensed to be administered in this way before recommending that tablets are crushed or capsules opened. The Summary of Product Characteristics sheet should be checked or the manufacturer of the drug contacted to obtain this information. This will ensure that pharmacists are undertaking best practice procedures to help ensure positive patient outcomes.

CHANGES IN 'SPECIALS' PRICING LEGISLATION

Recent changes in legislation affecting 'Specials' now allow the publication of price lists, which it is hoped will lead to greater transparency in pricing policies. There can sometimes be a considerable variation in the price paid for 'Specials' due to the supply chain, which does not always accurately reflect the ex-factory price from the manufacturer. So purchasing directly from the manufacturer offers the best value for money for the NHS.

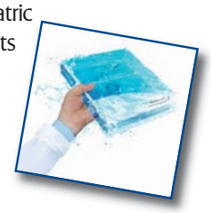
Even before the legislative changes, Rosemont's 'Specials' pricing policy has been to supply a list of all 'Specials' prices to healthcare professionals on receipt of a signature. The changes in regulations now mean that Rosemont can openly publish this price list, without having to ask the healthcare professional to sign for it. Any pharmacist ordering directly from Rosemont is guaranteed to pay the price set out on the published price list.

GOOD FOR NOTHING

(THE ROSEMONT PRODUCT REFERENCE GUIDE, ALL OF OUR KNOWLEDGE DELIVERED FOR FREE.)

The Rosemont Product Reference Guide contains detailed specifications for all 131 products in our range.

This free comprehensive source with a wealth of information on our liquid medicines will be a handy guide to help you follow best practice. Whether you are dealing with vulnerable paediatric or elderly patients, who find tablets or capsules hard to swallow.



To get your free copy simply call 0113 244 1400, fax 0113 245 3567 or email infodesk@rosemontpharma.com

You can also find our product specifications on-line at www.rosemontpharma.com