

June **MIMS** Monthly Medicine Update

NEW PRODUCTS

Coveram (perindopril arginine +amlodipine besylate) is a new product combining an ACE inhibitor and calcium channel blocker. It is indicated as substitution therapy for the treatment of hypertension and/or stable coronary heart disease in patients already controlled with separate doses of perindopril and amlodipine, given concurrently at the same dose level. Treatment should not be initiated with this combination. Coveram is contraindicated in bilateral or unilateral renal artery stenosis, severe hypotension, shock, including cardiogenic shock, angina pectoris (excluding Prinzmetal's angina), obstruction of the outflow-tract of the left ventricle (e.g. high grade aortic stenosis), unstable heart failure after acute myocardial infarction (during the first 28 days), haemodialysis patients using high-flux polyacrylonitrile membranes, pregnancy and lactation. The recommended dose is one tablet daily as a single dose, preferably in the morning, before a meal. Coveram is available as 5 mg/5 mg, 5 mg/10 mg, 10 mg/5 mg and 10 mg/10 mg tablets (30's) as a PBS Restricted Benefit item [Hypertension in a patient who is not adequately controlled with either of the drugs in the combination; stable coronary heart disease in a patient who is stabilised on treatment with perindopril and amlodipine at the same doses.]

Prevenar 13 is a pneumococcal polysaccharide conjugate vaccine, 13-valent adsorbed, containing serotypes 1, 3, 4, 5, 6A, 6B 7F, 9V, 14, 18C, 19A, 19F and 23F. It is indicated for active immunisation in the prevention of disease caused by *Streptococcus pneumoniae* (serotypes as above) including invasive disease, pneumonia and acute otitis media, in infants and children from 6 weeks up to 5 years of age. It is contraindicated in hypersensitivity to diphtheria toxoid and allergic or anaphylactic reaction following prior administration of Prevenar. Administration is only by intramuscular injection into the anterolateral thigh (infants) or deltoid muscle (young children). The primary infant series consists of three doses, each of 0.5 mL, with the first dose usually given at 6 weeks of age and with an interval of at least one month between doses. Refer to the full PI and national immunisation schedule for further information. Prevenar 13 is available on private prescription in 0.5 mL pre-filled syringes in packs of 1 and 10's.

SMOFlipid is an emulsion for intravenous infusion containing soya oil, medium-chain triglycerides, olive oil and fish oil. It is indicated as a supply of energy and essential fatty acids to patients, as part of a

parenteral nutrition regimen, when oral or enteral nutrition is impossible, insufficient or contraindicated. SMOFlipid is contraindicated in hypersensitivity to fish, egg, soya or peanut protein, severe hyperlipidaemia, severe liver insufficiency, severe blood coagulation disorders, severe renal insufficiency without access to haemofiltration or dialysis, acute shock, acute pulmonary oedema, hyperhydration, decompensated cardiac insufficiency and unstable conditions (e.g. severe post-traumatic conditions, uncompensated diabetes mellitus, acute myocardial infarction, stroke, embolism, metabolic acidosis and severe sepsis and hypotonic dehydration). The patient's ability to eliminate the fat infused should govern the dosage and infusion rate, see full PI. SMOFlipid 20% is available in single bags of 100 mL, 250 mL and 500 mL.

NEW INDICATIONS

Risperdal Consta (**risperidone**) is now indicated as adjunctive maintenance treatment with lithium or sodium valproate in the treatment of refractory patients with bipolar I disorder who have at least 4 relapses in a 12 month period. It is also now indicated as monotherapy for maintenance treatment to prevent the recurrence of manic or mixed episodes of bipolar I disorder in patients with a manic or mixed episode, following stabilisation with oral risperidone.

NEW FORMULATIONS

Fosamax Plus D-Cal is a new combination pack containing Fosamax Plus tablets (**alendronate sodium +colecalciferol**) and BoneCal tablets (**calcium carbonate**). Fosamax Plus D-Cal is indicated for the treatment of osteoporosis in select patients where vitamin D and calcium supplementation is recommended. Additional contraindications (due to the BoneCal component) include hypercalcaemia and severe hypercalciuria. The recommended dose is one tablet of Fosamax Plus 70 mg/140 mcg taken once weekly followed by 1one or two BoneCal tablets daily (with food) for the next 6 days. This 7 day cycle should be repeated each week. The Fosamax Plus component should always be taken on the same day each week. The BoneCal component should commence on the day after the Fosamax Plus tablet is taken. The Fosamax Plus and BoneCal tablets should never be taken at the same time. Standard alendronate dosing precautions apply. Fosamax Plus D-Cal comes as a 28 Day combination pack containing Fosamax Plus 70mg/140 mcg, providing 5600 IU vitamin D3 (4's) and BoneCal tablets providing 500mg elemental calcium (48's). It is available as a PBS Streamlined Authority item [2645: Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged

70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less; 2646: Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma].

SAFETY RELATED CHANGES

Postmarketing reports with **atorvastatin** (Lipitor) and fusidic acid have included severe muscle problems such as rhabdomyolysis. Although interaction studies with this combination have not been conducted, patients should be closely monitored and temporary suspension of atorvastatin treatment may be appropriate.

In clinical studies, the use of **everolimus** (Certican) has been associated with an increased frequency of surgical complications attributed to impaired wound healing. Such complications include lymphocele, wound dehiscence, wound infections, and pleural and pericardial effusion in cardiac transplant recipients. There is evidence in the literature to suggest that such events may be more frequent in patients with elevated body mass index.

This list is a summary of only some of the changes that have occurred over the last month. Before prescribing always refer to the full Product Information