

# Newly Registered Products

## anistreplase

recombinant human tissue plasminogen-streptokinase activator (TPSA)  
Eminase®: Beecham Laboratories, Ireland  
solution for injection 30 IU/ampoule

*Indications:* Acute myocardial infarction.

*Contraindications:* Risk of haemorrhage.

*Precautions:* Safety of use during pregnancy and lactation not established.

*Adverse reactions:* Bleeding, flushing, bradycardia, hypotension, fever, nausea, vomiting and allergic reactions, including rashes, occasional bronchoconstriction, and anaphylaxis have been reported.

## batroxobin

fibrinolytic enzyme, derived from snake venom  
Defibrase®: Tobishi, Japan

solution for IV infusion: 10 units/ampoule

*Indications:* Exacerbation of peripheral arteriosclerotic vascular disease. Sudden nerve deafness attributed to intra-arterial thrombosis.

*Contraindications:* Risk of haemorrhage. Severe hepatic or renal impairment. Hypersensitivity.

*Caution* is required in the elderly and patients on anticoagulants or antithrombotic drugs.

*Precautions:* Monitoring of hepatic enzymes, renal function and of signs of spontaneous haemorrhage required. Safety of use in pregnancy, lactation and in children has not been established.

*Adverse effects:* Gastrointestinal symptoms, rash, urticaria, dizziness, headache, haemorrhagic episodes, chest pain and shock have been reported.

## pravastatin

antihyperlipidaemic  
Mevalotin®: Sankyo, Japan

tablet 5 mg; granules 0.5%

*Indications:* Hyperlipidaemia, hypercholesterolaemia.

*Contraindications:* Hypersensitivity.

*Caution* in patients with liver dysfunction.

*Precautions:* Safety in pregnancy, lactation, and in children has not been established.

*Adverse effects:* Skin rashes, diarrhoea, abdominal pain, gastric discomfort and impairment of hepatic and renal function have been reported

## ramipril

angiotensin-converting enzyme (ACE) inhibitor

Triatec®: Hoechst, France.

Trilace®: Hoechst, Ireland.

capsules 1.25, 1.5, 5, 10 (Ireland only) mg

*Indications:* Mild to moderate hypertension.

*Contraindications:* Known hypersensitivity.

*Precautions:* Safety has not been established during pregnancy and lactation, or in children. Ability to drive or operate machines may be impaired.

*Caution* required in hepatic or renal impairment.

*Adverse effects:* Nausea, vertigo, headache, gastrointestinal pain have been reported.

## rilmazafone

hypnotic sedative

Rhythmy®: Shionogi, Japan

tablet 1, 2 mg

*Indications:* Insomnia, preanaesthetic medication.

*Contraindications:* Acute narrow-angle glaucoma, myasthenia gravis. Children, women of child-bearing potential, and during lactation. Caution is required in patients with pulmonary insufficiency or cerebrovascular accidents.

*Caution* in patients with cardiac, hepatic or renal impairment or with organic brain disorders, and in the elderly.

*Precautions:* Patients should not drive or operate machinery. Hepatic and renal function should be monitored.

*Adverse effects:* Skin rashes, disorders of the central nervous system, diarrhoea, abdominal pain and gastric discomfort have been reported.