Imdex™ 60 mg CR tablets

COMPOSITION
Imdex™ is a controlled release formulation of Isosorbide-5-mononitrate. The active substance is released independently of pH.

Each Imdex™ 60 mg CR tablet contains 60 mg Isosorbide-5-mononitrate, excipients and colouring agents (iron oxide, titanium dioxide and quinoline yellow aluminium lake), qs.

PHARMACOLOGY/ PHARMACOKINETICS
The principal pharmacological action of Isosorbide-5-mononitrate is relaxation of vascular smooth muscle, producing signifi-cant vasodilator activity; the strongest effect being exerted on the venous system and a lesser effect on the arterial circulation. As a consequence, the heart has less work to perform against diminished resistance and therefore oxygen requirement is reduced.

Isosorbide-5-mononitrate is readily absorbed from the gastro-intestinal tract and does not undergo first-pass hepatic metabolism and bioavailability is nearly 100%. The rate of absorption is slowed by food but overall bioavailability is unchanged. Kinetics of Isosorbide-5-mononitrate are not significantly influenced by advancing age, hepatic or renal disease.

Isosorbide-5-mononitrate is widely dis-tributed with a large apparent volume of distribution. It undergoes nearly total elimination in the liver by denitration and conjugation to form Isosorbide and Isosorbide glucuronide as inactive metabolites. Only 2% of Isosorbide mononitrate is excreted unchanged in the urine with an elimination half-life of around 5 hours.

INDICATIONS
Imdex™ tablets are indicated for the prophy-laxis and long-term treatment of angina pectoris due to coronary artery disease.

SIDE EFFECTS/ADVERSE REACTIONS
Most adverse effects are dose-related. Tachycardia, palpitations and orthostatic hypotension are common symptoms. These symptoms generally disappear during continued treatment. Headache may occur during initial treatment, but usually disappear with continued treatment.

PRECAUTIONS/WARNINGS
Imdex™ should be used with caution in patients with severe hepatic or renal impairment, hypothyroidism, malnutrition,hypothermia or with a recent history of myocardial infarction.

The use of Imdex™ during *pregnancy* and *breast-feeding* is not recommended due to lack of information.

Geriatrics:
Elderly patients may be more sensitive to the hypotensive effects of nitrates. In addition, they are more likely to have age-related renal function impairment, which may require caution in patients receiving nitrates.

Nitrate tolerance:

> Development of tolerance may occur with all forms of nitrate therapy particularly with the long acting nitrate preparations that maintain continuously high plasma nitrate concentration.

eg. by taking more than 120 mg/day of Imdex™ and / or twice daily dosage, the risk of development of tolerance may occur. It is therefore very important that Imdex™ should be taken once a day in order to achieve a period of low nitrate concentration at night, reducing the risk of development of tolerance.

Size: 14.8cm (w) x 21cm (H)

Blck100%

Withdrawal of nitrates should be gradual to avoid precipitation of acute angina.

CONTRAINDICATIONS
Isosorbide-5-mononitrate is contraindicated in patients who are allergic to nitrates and in cases of low blood pressure, hypovolaemia, shock, marked anaemia, closed-angle glaucoma and raised intracranial pressure due to head trauma or cerebral haemorrhage. Imdex™ should also not be used in patients with hypertrophic obstructive cardiomyopathy, aortic stenosis, cardiac temponade, constrictive pericarditis, mitral stenosis and acute myocardial infarction with low left ventricular filling pressure.

DRUG INTERACTIONS
Orthostatic hypotension may occur with the combined use of calcium channel blockers, antihypertensive agents, phenothiazines and tricyclic antidepressants. Use of alcohol with Isosorbide-5-mononitrate may produce severe hypotension and collapse.

RECOMMENDED DOSAGE, DOSAGE SCHEDULE AND ROUTE OF ADMINISTRATION
Adult dose:
Imdex™ 60 mg, once daily to be taken in the morning. The dose may be increased to 120 mg once daily in the morning. To minimise the possibility of headache, treatment can be initiated with 30 mg for the first 2-4 days. Whole tablet of Imdex™ 60 mg and 30 mg tablets should be swallowed with half a glass of fluid. If required, the divided half of Imdex™ 60 mg should also be taken in the same manner. Care has to be taken to avoid crushing or chewing the tablet, in order for half tablet doses to be administered without affecting its sustained release properties.

Dosage of elderly:
The dosage of nitrates in cardiovascular disease is usually determined by patient response and stabilisation. However, caution may be required in elderly patients who are known to be susceptible to the effects of hypotensive medication.

Children:
The safety and efficacy of Imdex™ in children has not been established.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE, AND ANTIDOTE(S)
Acute overdosage
Overdose symptoms include hypotension, tachycardia, warm flushed skin, headache, restlessness and nausea.

Treatment:
Induce emesis or perform gastric lavage followed by charcoal administration. Hy potension is managed by elevating the legs and administration of intravenous fluids. If necessary an -adrenergic agonist such as methoxamine or phenylephrine may be used.

PHARMACEUTICAL INFORMATION
• Dosage forms and Strength
60 mg controlled released tablets.

• Storage conditions
Store below 30°C in a cool dry place.
Protect from light.
Keep medicines out of reach of children.
Jauhkan ubat-ubatan daripada kanak-kanak.

• Shelf life
Please refer to outer package

• Pack size/package
Blister packs of 14's x 2
Blister packs of 14's x 50

• Product description
Imdex 60 mg CR tablet: Yellow, oval, biconvex, film coated, scored on one side and marked with IM on the other side. side.

Product Registration Holder:
Duopharma (Singapore) Pte. Ltd.
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#03-53 German Centre, Singapore 609916

Manufacturer:
DUOPHARMA MANUFACTURING (BANGI) SDN. BHD.
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