For the use of a registered medical practitioner or a hospital or a laboratory only

Isosorbide-5-mononitrate
Imdur® 30/60mg
Abbreviated Prescribing Information

Composition: Each prolonged release film coated contains Isosorbide-5-mononitrate 30 & 60mg

Description: Isosorbide-5-monontrate (Imdur®) is an active metabolite of isosorbide dinitrate and exerts qualitatively similar effects. Imdur® relaxes vascular smooth muscle resulting in vasodilation. The predominant action is the dilatation of the veins, which leads to a reduction of the venous return and an unloading of heart. Imdur® also dilates the systemic arteries and large coronary arteries. The net effect when administering Imdur® is therefore a reduced work-load of the heart and an improved oxygen supply/demand balance in the myocardium.

Indication: indicated for prophylactic treatment of angina pectoris.

Posology and method of administration:

30 or 60 mg once daily to be taken in the morning. The dose may be increased to 120 mg daily, taken once daily in the morning. The dose can be titrated to minimize the possibility of headache by initiating treatment with 30 mg for the first 2-4 days. The tablets can be taken with or without food. The 30 or 60 mg depotablets are scored and dividable. The whole tablets or if needed the divided halves, should not be chewed or crushed and should be swallowed together with half a glass of fluid. Imdur is not indicated for the relief of acute attacks. In these situations sublingual or buccal nitroglycerine tablets or spray formulations should be used. The matrix of the tablet is insoluble but disintegrates when the active substance is released. Occasionally the matrix may pass through the gastrointestinal tract without disintegrating and may be visible in the stool but this does not indicate that the drug has had a reduced effect.

Contraindication: Hypersensitivity to the active substance or to any of the excipients, shock, hypotension, constrictive cardiomyopathyand pericarditis. Patients treated with Imdur must not be given Phosphodiesterase type 5 Inhibitors (e.g. sildenafil).

Special warnings and precautions for use: Caution should be observed in patients with severe cerbral arteriosclecrosis and hypotension.

Pregnancy and lactation: The safety and efficacy of Imdur® during pregnancy or lactation have not been established.

Adverse effects: Headache may occur when treatment is initiated but usually disappears during continued treatment. Hypotension, with symptoms such as dizziness and nausea, has occasionally been reported. These symptoms generally disappear during continues treatment.

List of excipients:

Imdur Durules 30 mg tablets : Sodium aluminium silicate, paraffin, hydroxypropylcellulose, magnesium stearate, colloidal silicon dioxide, hypromellose, macrogol, red iron oxide (E172), titanium dioxide (E171). Imdur Durules 60 mg tablets: Sodium aluminium silicate, paraffin.

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hydroxypropylcellulose, magnesium stearate, colloidal silicon dioxide, hypromellose, macrogol, yellow iron oxide (E172), titanium dioxide (E171).

Special precautions for storage
Store in a cool, dry place.
Shelf-life
Please see outer pack.
Presentation: Imdur 30 & 60 mg Tablets-Strip of 10 tablets.

IMDUR® is a registered trademark of AstraZeneca Group of companies.

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For more information refer full prescribing information Version 2 Dated 1st February 2015