尊敬的客户，本稿件涉及到的信息将作为我司生产的法定依据，请贵司涉及到的相关人员务必仔细校对及填写相关要素，
若有疑问请致电 028-87334186 我司技术人员会为您悉心解答。谢谢！

	设计部 TEL：028-87334186					电子监管码
客户名称	TopRidge Pharma (Ireland) Limited	产品名称	马来西亚 Imdur 30mg+60mg 说明书			请客户确认喷码样式
电子文件序号	Z03005433_1_01	成品尺寸（LBH）	140*380mm	规 格	30+60mg	
分 色	单黑单面印刷	表面工艺		成型标准		
跟色标准	正常四色	包装方式	机包	制稿单位	四川汇利实业有限公司	
材质克重	60克双胶	折页方式		卷标方向		
打码方式		制作人/日期	石利敏 2024.07.30	客户确认人/日期		
备 注						

请仔细校对文字、图案、条码、尺寸、盒型。确认后请填写以上生产必要要素如需修改请联系设计部,确认无误请签字确认!

如果贵司产品为“机包盒”，请着重确认三期位置、监管码位置及盒型结构!

140mm

380mm

Imdur®

Isosorbide-5-mononitrate
Tablets 30 mg & 60 mg

Qualitative and Quantitative Composition
One prolonged release tablet contains: isosorbide mononitrate 30 mg or 60 mg.
For excipients see **List of excipients.**

Pharmaceutical Form
Prolonged release tablet
30 mg: Pink, oval with score, marked A/II, 7x13mm.
60 mg: Pale yellow, oval with score, marked A/ID, 7 x 13 mm.

Therapeutic indications
Prophylactic treatment of angina pectoris.

Posology and method of administration
Imdur is intended for prophylactic treatment. The dosage is individual and must be titrated according to clinical response. Imdur prolonged release tablets are taken once daily, in the morning.

When initiating treatment, in order to avoid headache, 30 mg may be given for the first 2-4 days.

Normal dosage: 60 mg daily. If necessary the dose may be increased to 120 mg daily.

There is a risk of tolerance development with nitrate therapy. It is therefore important that Imdur is taken once daily in order to obtain intervals with low nitrate concentrations and thus reduce the risk of tolerance development.

If necessary, Imdur may be combined with beta-adrenoreceptor blockers and calcium antagonists.

Administration
The tablets for the lower strengths, 30 and 60 mg, are dividable. The whole or divided tablet should not be chewed or crushed and should be swallowed together with ½ glass of fluid.

Contraindications
Shock, hypotension, constrictive cardiomyopathy, constrictive pericarditis and pericardial tamponade.

Hypersensitivity to the active ingredient or any excipients. Concomitant treatment with Phospodiesterase type 5 Inhibitors (e.g. sildenafil).

Special warnings and special precautions for use
Caution should be exercised in treatment of patients with serious cerebrovascular disease, increased intracranial pressure, aortic stenosis, mitral stenosis and hypertrophic obstructive cardiomyopathy, anaemia, hypoxaemia and hypothyroidism.

Interaction with other medicinal products and other forms of interaction
The following combination with Imdur must be avoided:
Phospodiesterase type 5 Inhibitors (e.g. sildenafil): Administration of Phospodiesterase type 5 Inhibitors (e.g. sildenafil) is contraindicated to existing treatment with nitroglycerin products since it may lead to serious fall in blood pressure, ischaemia and circulatory disorders with permanent heart and brain damages.

Use during pregnancy and lactation
Pregnancy
Clinical experience from pregnant women is limited. Experimental animal data do not indicate an increased risk of foetal damage.
Lactation
No information is available regarding passage into breast milk.

Effects on ability to drive and use machines
Since dizziness may be experienced in Imdur treatment this should be considered when strict attention is required e.g. when driving cars or operating machines.

Undesirable effects
The majority of side effects are pharmacologically mediated and dose dependent. Headache may occur in about 25 % of the patients when treatment is initiated. This side effect is due to the vasodilatory effect of the product but usually disappears within a week. The headache can be avoided when 30 mg is given the first 2-4 days.

A fall in blood pressure may lead to reflectory tachycardia, dizziness and fainting.

Frequency / Organ	Very common (>1/10)	Common (>1/100, <1/10)	Less common (>1/1000, <1/100)	Rare (>1/10000, <1/1000)	Very rare (<1/ 10000)
General		headache, dizziness		fainting	
Circulation		hypotension, tachycardia			
Gastroint -estinal		nausea	vomiting, diarrhoea		
Skin				rash, pruritus	
Musculos-keletal					myalgia

Overdose
Limited experience. 20 mg given to a 2-year old and a 5-year old did not cause any symptoms.

Symptoms: Pulsing headache. Excitation, flushing, cold perspiration, vomiting, dizziness, syncope, tachycardia, palpitations and fall in blood pressure.

Very large doses may cause methaemoglobinaemia (very rare).

Treatment: If necessary gastric lavage, charcoal. If fall in blood pressure occurs intravenous fluid should be given at first hand. (Methyltionin 1-2 mg/kg should be given slowly intravenously in cyanosis as a consequence of methaemoglobinaemia). Symptomatic treatment.

Pharmacological Properties

Pharmacodynamic properties
Pharmacotherapeutic group: Vasodilators in heart diseases, organic nitrates
ATC- code: C01DA14

Imdur is a prolonged release dosage form of isosorbide-5-mononitrate, which is an active metabolite of isosorbide dinitrate. Nitrate compounds produce a dose-dependent relaxation of smooth muscle. The effect of treatment is dependent on the dose and individual sensitivity. Low doses produce dilatation of the veins and reduced venous reflux to the heart (reduced preload). High doses in addition cause arterial dilatation and reduced vascular resistance (reduced afterload). Isosorbide-5-mononitrate reduces the work of the heart as a result of venous and arterial dilatation and may also have a direct dilating effect on coronary vessels. By reducing end diastolic pressure and volume, the preparation lowers the intramural pressure, which leads to an improvement of subendocardial perfusion. The net effect of isosorbide-5-mononitrate is reduced heart work and improved myocardial oxygen saturation.

Imdur is intended for prophylactic treatment of angina pectoris. The duration of effect, measured with exercise tests, is at least 12 hours. At this point in time the plasma concentration is at the same level as 1-2 hours after tablet intake (about 1300 nmol/litre).

In continuous treatment with nitrate compounds there is a risk of tolerance development, which varies from one individual to another. Imdur must therefore be administered once daily to obtain an interval with low nitrate concentration.

Imdur consists of an insoluble matrix, which usually disintegrates as a result of/through intestinal peristalsis. The tablet may therefore appear intact, whereas the active substance has dissolved during passage through the gastrointestinal tract.

Pharmacokinetic properties
The onset of effect occurs within an hour. The bioavailability of Imdur is about 90 %. Absorption is not affected by concomitant food intake. The release of active substance from Imdur is gradual and independent of pH, and is completed after about 10 hours. After repeated oral administration of 60 mg once daily, maximum plasma concentration (about 3000 nmol/litre) is achieved after about 4 hours. The plasma concentration then decreases, to be less than 500 nmol/litre at the end of the dosing interval (24 hours after ingestion). The volume of distribution of isosorbide-5-mononitrate is about 0.6 litres/kg and clearance is 115 ml/minute. Elimination takes place mainly by denitration and conjugation in the liver to inactive metabolites. The metabolites are excreted mainly via the kidneys. Only about 2 % of a given dose is excreted intact via the kidneys.

Impaired hepatic or renal function have no influence on the clinical effect.

Pharmaceutical Particulars

List of excipients
Sodium aluminium silicate, paraffin, hydroxypropylcellulose, magnesium stearate, anhydrous colloidal silicon dioxide, hypromellose, macrogol 6000, titanium dioxide (colouring agent E 171), iron oxide (colouring agent E172, 30 mg and 60 mg prolonged release tablets).

Incompatibilities
Not applicable.

Shelf life
3 years

Special precautions for storage
Store below 30°C .

Nature and contents of container
Blister (aluminium/PVC):
Prolonged release tablets 30 mg (30 tablets)
Blister (aluminium/PVC/PVDC):
Prolonged release tablets 60 mg (30 & 105 tablets)

Instructions for use, handling and disposal
No special requirements.

Manufacturer
Laboratorios Alcalá Farma, S.L.
Avenida de Madrid, 82, Alcalá de Henares, Madrid, 28802, Spain

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August 2024.

TopRidge