

Imdur®

Isosorbide-5-mononitrate 30mg, 60mg

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What Imdur® is used for

Imdur is used as preventive treatment of vascular spasm in the heart (angina pectoris).

How Imdur® works

Imdur works by widening the blood vessels and so making the work of the heart easier in the case of vascular spasm in the heart.

Before you take Imdur®

- When you must not take it

You must not use Imdur in the following cases :

- in shock
- in low blood pressure
- in disease of the heart muscles (constrictive cardiomyopathy)
- in certain diseases of the pericardium (constrictive pericarditis, pericardial tamponade)
- at the same time as phosphodiesterase type 5 inhibitors, such as Viagra (sildenafil), Cialis (tadalafil) and Levitra (vardenafil)
- if you are hypersensitive to any of the ingredients

- Before you start use it

Talk to your doctor before you start using Imdur if you suffer from any of the following:

- brain damage
- heart disease
- reduced oxygen level in the blood (hypoxaemia)
- blood deficiency (anaemia)
- reduced thyroid gland function (hypothyroidism)

- Taking other medicines

Inform your doctor if you are taking any other medication at the same time as Imdur. Certain medicines may affect or be affected by treatment with Imdur.

When you are treated with Imdur you must not use phosphodiesterase type 5 inhibitors, such as Viagra (sildenafil), Cialis (tadalafil) and Levitra (vardenafil), which are used for impotence (erectile dysfunction).

How to take Imdur®

- How much to take

Your doctor will determine the dose that is suitable for you. The usual dose is 60 mg once daily.

- When to take it

The tablets for the lower strengths, 30 mg and 60 mg, are divisible. Whole or divided tablets must not be chewed or crushed and must be swallowed with at least 1/2 a glass of fluid.

The contents of the Imdur tablet are surrounded by a shell that can pass unchanged through the bowel. The tablet may therefore appear completely intact, but the active substance is dissolved out on the way through the gastrointestinal tract.

- How long to take it

Do not stop taking your tablets, even if you are feeling well, unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- If you forget to take it

If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten dose.

- If you take too much (overdose)

If you take too large a dose of the medicine always contact your doctor, hospital for assessment of the risk and advice.

While you are using Imdur®

- Things you must do

Take your medication as advised by your doctor or pharmacist.

- Things you must not do

Do not stop taking the medication unless being told by your doctor or pharmacist.

- Things to be careful of

Pregnancy

There is limited experience of use in pregnancy. Therefore talk to your doctor in the case of more than occasional use of Imdur during pregnancy.

Breast-feeding

It is not known whether isosorbide mononitrate is transferred into breast milk. Therefore talk to your doctor before regular use of Imdur while breast-feeding.

Driving and operating machinery

Imdur can impair the ability to react, as you may experience

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dizziness when taking the medicine. You should bear this in mind when driving or operating machinery.

Side effects

Side effects may occur, but it is not certain that you will experience any of them.

Common: (affects more than 1 person in 100): headache, low blood pressure which may cause dizziness and nausea, increased pulse. The headache disappears after a few weeks of treatment.

Uncommon: vomiting, diarrhoea.

Rare: (affects less than 1 person in 1000): fainting attack, skin rash, itching.

Isolated cases of muscle pain (myalgia) have been reported.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → *Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety*).

Storage and Disposal of Imdur[®]

- Storage

Keep out of the reach and sight of children

Use before the expiry data that is stated on the packaging.

- Disposal

Please check with your pharmacist on how you should dispose your medicine.

Product Description

Prolonged release tablets 30 mg:
pink, oval with break line, marked A/II.

Prolonged release tablets 60 mg:
pale yellow, oval with break line, marked A/ID.

- Ingredients

Active ingredient(s)

Isosorbide mononitrate 30 mg or 60 mg.

Inactive ingredients:

magnesium stearate, silicon dioxide, paraffin, hypromellose, hydroxypropyl cellulose, sodium aluminium silicate, macrogol, colouring (titanium dioxide E171), colouring 30 and 60 mg prolonged release tablets (iron oxide E172).

- Malaysia Registration Number:

Imdur 30mg tablet:
MAL19940091ACZ

Imdur 60mg tablet:
MAL19940090ACZ

Manufacturer

Laboratorios Alcalá
Farma, S.L.
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Alcalá de Henares,
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Product Registration Holder:

Zuellig Pharma Sdn Bhd

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