

Package leaflet: Information for the user
Imdur® 60 mg Prolonged-release, Film-coated Tablets
Isosorbide mononitrate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Imdur is and what it is used for
2. What you need to know before you take Imdur
3. How to take Imdur
4. Possible side effects
5. How to store Imdur
6. Contents of the pack and other information

1. What Imdur is and what it is used for

Imdur contains a medicine called isosorbide mononitrate. This belongs to a group of medicines called ‘nitrates’.

- It is used to prevent chest pain (angina).
- It works by making the blood vessels relax and widen. This makes it easier for the heart to pump blood around the body.

The tablets are made so that they release the medicine slowly over a number of hours.

2. What you need to know before you take Imdur

Do not take Imdur:

- If you are allergic to isosorbide mononitrate or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to any other nitrate medicines. These include glyceryl trinitrate and isosorbide dinitrate.
- If you have ever had a stroke.
- If you have very low blood pressure.
- If you have severe anaemia.
- If you have a heart problem called ‘cardiomyopathy’ or ‘pericarditis’ or you have narrow heart valves.
- If you have recently had a head injury, which may have caused bleeding in your brain.
- If you may have ‘hypovolaemia’. Symptoms may include faster breathing or pulse, with sweating.
- If you are taking sildenafil or similar medicines called Phosphodiesterase Type 5 Inhibitors, (used for male impotence). See the section “Taking other medicines”.

Do not take Imdur if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Imdur.

Warnings and precautions

Talk to your doctor or pharmacist before taking Imdur:

- If you have ever had any serious damage to your heart, such as a heart attack or operation.
- If you have a very low body temperature (hypothermia).
- If you have not been eating properly (malnutrition).
- If you have an underactive thyroid gland (hypothyroidism).
- If you have severe liver or kidney problems.

If any of the above apply to you, or if you are not sure if they do, talk to your doctor or pharmacist before taking Imdur.

Other medicines and Imdur

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Imdur can affect the way some medicines work and some medicines can have an effect on Imdur.

Do not take Imdur if you are taking the following medicines:

- Sildenafil or similar medicines called Phosphodiesterase Type 5 Inhibitors, (used for male impotence).

In particular, tell your doctor or pharmacist if you are taking the following medicines:

- Medicines for high blood pressure or heart problems called vasodilators, such as ACE inhibitors, beta-agonists or calcium channel blockers.

If any of the above applies to you, or if you are not sure if they do, talk to your doctor before taking Imdur.

Imdur with food, drink and alcohol

Avoid alcohol whilst taking Imdur. It may affect the way Imdur works.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

You may feel dizzy after taking Imdur. If this happens, do not drive or use any tools or machines.

3. How to take Imdur

Always take Imdur exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Swallow the tablets whole or broken in half (if this is easier to swallow).
- Take the tablets with half a glass of water.
- Do not crush or chew the tablets.

How much to take

- The recommended dose is one or two tablets a day.
- Take the medicine in the morning.
- Your doctor may ask you to start on a low dose so that you are less likely to have a reaction to starting Imdur.
- The blister strips are marked with the days of the week. If you are taking two tablets a day, make sure you take one tablet from each strip marked with the same day of the week.

You must not take Imdur for a sudden attack of angina. If you have a sudden attack, take a glyceryl trinitrate tablet (follow the instructions given on the label).

Very occasionally, some people see the remains of the tablet in their bowel motions. This is quite normal and does not mean that the medicine has not been released.

Use in children

Do not give these tablets to children.

If you take more Imdur than you should

If you take more Imdur than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you so the tablets can be identified.

If you forget to take Imdur

- If you forget a dose, take it as soon as you remember it. 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 have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

- Headaches.
- Feeling sick (nausea).
- Feeling dizzy.

The above problems usually disappear with time.

Other possible side effects:

Common (may affect up to 1 in 10 people)

- Low blood pressure. This may make you feel faint or dizzy.
- Faster heartbeat.
- Headache.
- Feeling dizzy.
- Feeling sick (nausea).

Uncommon (may affect up to 1 in 100 people)

- Being sick (vomiting).
- Diarrhoea.

Rare (may affect up to 1 in 1,000 people)

- Fainting.
- Rash.
- Itchy skin.

Very rare (may affect up to 1 in 10,000 people)

- Pain in muscles.

Do not be concerned by this list of possible side effects, you may not get any of them. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland:

HPRA Pharmacovigilance

Earlsfort Terrace

IRL – Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

Malta:

ADR Reporting

The Medicines Authority

Post-Licensing Directorate

203 Level 3, Rue D'Argens

GŻR-1368 Gzira

Website: www.medicinesauthority.gov.mt

e-mail: postlicensing.medicinesauthority@gov.mt

5. How to store Imdur

- Keep this medicine out of the sight and reach of children.
- Do not store above 30°C.
- Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Imdur contains

- The active substance is isosorbide mononitrate. Each tablet contains 60 mg of the active substance.
- The other ingredients are aluminium silicate, paraffin special, hypromellose, magnesium stearate, colloidal anhydrous silica, hypromellose, macrogol 6000, titanium dioxide and iron oxide.

What Imdur looks like and contents of the pack

Imdur 60 mg Tablets are yellow, with 'A/ID' written on one side. They come in blister strips containing 7 tablets, which have the days of the week shown.

A pack may contain either 7, 14, 28 or 98 tablets as multiples of the 7 tablet blister strip.

Imdur 60 mg Tablets may also come in glass bottles of 100 tablets.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for Imdur 60 mg Prolonged-release, Film-coated Tablets marketed in Ireland is held by TopRidge Pharma (Ireland) Limited, 6-9 Trinity Street, Dublin 2, Ireland.

The Marketing Authorisation for Imdur 60 mg Prolonged-release, Film-coated Tablets marketed in Malta is held by TopRidge Pharma (Ireland) Limited, 6-9 Trinity Street, Dublin 2, Ireland.

Imdur 60 mg Prolonged-release, Film-coated Tablets are manufactured by Laboratorios Alcalá Farma, S.L. Avenida de Madrid, 82, Alcalá de Henares, Madrid, 28802, Spain.

Leaflet prepared: December, 2017