

PACKAGE LEAFLET: INFORMATION FOR THE USER

Half-Inderal® LA 80mg Prolonged-release Capsules (propranolol hydrochloride)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

1. What Inderal is and what it is used for
2. Before you take Inderal
3. How to take Inderal
4. Possible side effects
5. How to store Inderal
6. Further information

1. What Inderal is and what it is used for

The name of your medicine is Half-Inderal LA Prolonged-release Capsules 80mg (called Inderal in the rest of this leaflet). Inderal contains a medicine called propranolol hydrochloride. This belongs to a group of medicines called beta-blockers.

Inderal is used for many conditions including:

- High blood pressure (hypertension).
- Chest pain (angina).
- Protecting the heart after a heart attack.
- Preventing migraines.
- Essential tremor (shaking with an unknown cause).
- Anxiety.
- Some thyroid problems (such as thyrotoxicosis which is caused by an overactive thyroid gland).
- Prevention of bleeding in the food pipe (oesophagus) caused by high blood pressure in the liver.

It works by the effects it has on the heart and circulation and also on other parts of the body.

2. Before you take Inderal

Do not take Inderal if:

- **You or anyone in your family has ever had asthma or wheezing.**
- You are allergic (hypersensitive) to propranolol hydrochloride or any of the other ingredients in Inderal (see section 6: Further information).

- You have ever had any of the following heart problems:
 - heart failure which is not under control (this usually makes you breathless and causes your ankles to swell)
 - second- or third-degree heart block (a condition which may be treated by a pacemaker)
 - very slow or very uneven heart beats, very low blood pressure or very poor circulation
 - a type of chest pain (angina) called Prinzmetal's angina.
- You have a tumour called phaeochromocytoma that is not being treated. This is usually near your kidney and can cause high blood pressure.
- You have been told that you have higher than normal levels of acid in your blood (metabolic acidosis).
- You have been fasting recently.

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

Take special care with Inderal

Check with your doctor or pharmacist before taking Inderal if:

- You get allergic reactions, for example to insect stings. It is important to tell your doctor you are taking Inderal if you need treatment for an allergic reaction.
- You have poor blood circulation or controlled heart failure.
- You have first-degree heart block.
- You have problems with your kidneys. You may need to have some check-ups during your treatment.
- You have problems with your liver (such as cirrhosis of the liver). You may need to have some check-ups during your treatment.
- You have diabetes. Your medicine may change how you respond to having low blood sugar. You may feel your heart beating faster.
- You have thyrotoxicosis (a condition caused by an overactive thyroid gland). Your medicine may hide the symptoms of thyrotoxicosis.

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

Taking other medicines

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

In particular, tell your doctor if you are taking any of the following medicines:

- Clonidine (for high blood pressure or migraine). If you are taking clonidine and Inderal together, do not stop taking clonidine unless your doctor tells you to do so. If you have to stop taking clonidine, your doctor will give you careful instructions about how to do it.
- Medicines such as Reserpine, Guanethidine or diuretics (water tablets) for high blood pressure (hypertension).
- Medicines for chest pain (angina).

- Disopyramide, lidocaine, quinidine, procainamide, amiodarone or propafenone (for an uneven heart beat).
- Digoxin (for heart problems).
- Warfarin (to thin the blood).
- Adrenaline, also known as epinephrine (a medicine that stimulates the heart).
- Ibuprofen or indometacin (for pain and inflammation).
- Ergotamine, dihydroergotamine or rizatriptan (for migraine).
- Chlorpromazine or thioridazine (for mental illness).
- Cimetidine (for stomach problems).
- Rifampicin (for tuberculosis).
- Theophylline (for asthma).
- Insulin (for diabetes).
- Medicines to treat nose or sinus congestion or other cold remedies (including those you can buy without a prescription).

Operations

If you go into hospital to have an operation, tell the anaesthetist or medical staff that you are taking Inderal. This is because you can get low blood pressure (hypotension) if you are given certain anaesthetics while you are taking Inderal.

Taking Inderal with food and drink

If you frequently drink a lot of alcohol, talk to your doctor before having this medicine. This is because alcohol can affect how the medicine works.

Pregnancy and breast-feeding

- Talk to your doctor before taking this medicine if you are pregnant, might become pregnant or are breast-feeding.
- Inderal should not be taken during pregnancy unless the doctor considers it essential.

Driving and using machines

- Your medicine is not likely to affect you being able to drive or use any tools or machines. However, it is best to wait to see how your medicine affects you before trying these activities.
- If you feel dizzy or tired when taking this medicine, do not drive or use any tools or machines.

Important information about some of the ingredients of Inderal Capsules

Inderal Capsules contain microcrystalline cellulose and titanium dioxide. These may cause a problem in a very small number of people who are sensitive to them.

3. How to take Inderal

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

- Your doctor will tell you how many capsules to take each day and when to take them. Read the label on the carton to remind you what the doctor said.
- Swallow your Inderal capsules with a drink of water. Swallow whole. Do not chew.

Adults

- **High blood pressure (hypertension):** the usual dose is 160mg a day. Your doctor may decide to increase this dose.
- **Chest pain (angina):** the usual dose is 80mg to 240mg a day.
- **To protect the heart after a heart attack:** the usual dose is 160mg a day.
- **To prevent migraine:** the usual dose is 80mg to 240mg a day.
- **Essential tremor:** the usual dose is 80mg to 240mg a day.
- **Anxiety:** the usual dose is 80mg to 240mg a day.
- **Thyroid conditions (such as thyrotoxicosis):** the usual dose is 80mg to 240mg a day.
- **Prevention of bleeding in the food pipe (oesophagus) caused by high blood pressure in the liver:** the usual dose is 80 mg to 320mg a day.

Elderly people

If you are an elderly person, your doctor may decide to start you on a lower dose.

Children

Your medicine must not be given to children.

If you take more Inderal than you should

If you take more Inderal than prescribed by your doctor, talk to a doctor or go to a hospital straight away. Take the medicine pack with you so that the capsules can be identified.

If you forget to take Inderal

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Inderal

Do not stop taking Inderal without talking to your doctor. In some cases, you may need to stop taking it gradually.

4. Possible side effects

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

Common (affects less than 1 in 10 people)

- You may notice that your pulse rate becomes slower while you are taking the capsules. This is normal, but if you are concerned please tell your doctor about it.
- Cold hands and feet.
- Numbness and spasm in your fingers which is followed by warmth and pain (Raynaud's disease).
- Disturbed sleep or nightmares.
- Feeling tired.

Uncommon (affects less than 1 in 100 people)

- Diarrhoea.
- Feeling sick (nausea).
- Being sick (vomiting).

Rare (affects less than 1 in 1,000 people)

- Heart block (which may cause an abnormal heart beat, dizziness, tiredness or fainting).
- Dizziness, particularly on standing up.
- Thinning of your hair.
- Mood changes.
- Feeling confused.
- Memory loss.
- Changes in personality (psychoses).
- Hallucinations.
- Tingling of your hands.
- Disturbances of vision.
- Dry eyes.
- Skin rash.
- Reduced numbers of platelets in your blood which may make you bruise more easily.
- Purplish marks on your skin.

Very rare (affects less than 1 in 10,000 people)

- Severe muscle weakness (myasthenia gravis).
- Changes to some of the cells or other parts of your blood. Your doctor may take blood samples every so often to check whether Inderal has had any effect on your blood.
- Low levels of sugar in the blood. This can happen in people with or without diabetes. This includes elderly people, people on artificial kidneys (haemodialysis) or people taking medicines for diabetes. It may also happen if you are fasting or in people with a long-term liver disease.

Conditions that may get worse

If you have any of the following conditions, they may get worse when you start to take your medicine. This happens rarely affecting less than 1 in 1,000 people.

- Psoriasis (a skin condition).
- Being short of breath or having swollen ankles (if you have heart failure).
- Asthma or breathing problems.
- Poor circulation.

Do not be concerned by this list of 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.

5. How to store Inderal

- Keep out of the reach and sight of children.
- Do not use your capsules after the expiry date (Exp) which is stated on the carton. The expiry date refers to the last day of that month.
- Store below 25°C. Store in the original package in order to protect from moisture and light.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.
- If your tablets appear to be discoloured, damaged or show any other signs of deterioration, please return these to your pharmacist who will advise you further.
- If you have any left-over/unused tablets, please return these to your pharmacist for safe disposal.

6. Further information

What Half-Inderal LA Prolonged-release Capsules 80mg contain

The active substance is propranolol.

Each prolonged release capsule contains 80mg of propranolol hydrochloride.

The other ingredients are erythrosine (E127), ethyl cellulose, gelatin, red iron oxide (E172), black iron oxide (E172), hypromellose, microcrystalline cellulose and titanium dioxide (E171).

What Half-Inderal LA 80mg capsules look like and contents of the pack

Half-Inderal LA 80mg capsules have an opaque pale lavender cap and a pink clear body, and are marked with 'Inderal LA - 80'. The capsules contain white to pale-cream coloured spheroids. They come in calendar packs containing 28 capsules.

Manufacturer

Manufactured by:
AstraZeneca UK Limited, Macclesfield, Cheshire, UK.

Procured from within the EU by the Parallel Product Authorisation holder: Imbat Ltd, Unit L2, North Ring Business Park, Santry, Dublin 9.

Repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

Distributed by: Eurodrug Ltd, Santry, Dublin 9.

PPA No: 1151/157/1

Leaflet revision and issue date (Ref): 06.12.12

Inderal® is a registered trademark of the AstraZeneca group of companies