

Package leaflet: Information for the user

Inderal 10 mg Film-coated Tablets propranolol hydrochloride

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 Inderal is and what it is used for
2. What you need to know before you take Inderal
3. How to take Inderal
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1. What Inderal is and what it is used for

The name of your medicine is Inderal 10 mg Film-coated Tablets (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).
- Some heart beat problems (arrhythmias).
- 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).
- High blood pressure caused by a tumour, usually near the kidney (phaeochromocytoma).
- Prevention of bleeding in the food pipe (oesophagus) caused by high blood pressure in the liver.

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

2. What you need to know before you take Inderal

Do not take Inderal if:

- **You or anyone in your family has ever had asthma or wheezing.**

- You are allergic to propranolol hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- 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

Warnings and precautions

Talk to 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.

Other medicines and Inderal

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 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 or medicines that you take by mouth 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.

Inderal with food, drink and alcohol

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, 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

- 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.

Inderal contains lactose

- Inderal contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Important information about Inderal

- Inderal Tablets also contain titanium dioxide. This may cause a problem in a very small number of people who are sensitive to it.

3. How to take Inderal

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Your doctor will tell you how many tablets 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 tablets with a drink of water.

Adults

- **High blood pressure (hypertension):** the usual dose is 160 mg to 320 mg a day. Your doctor may decide to increase this dose.
- **Chest pain (angina):** the usual dose is 80 mg to 320 mg a day.
- **Heart beat problems (arrhythmias):** the usual dose is 30 mg to 160 mg a day.
- **To protect the heart after a heart attack:** the usual dose is 160 mg a day.
- **To prevent migraine:** the usual dose is 80 mg to 160 mg a day.
- **Essential tremor:** the usual dose is 80 mg to 160 mg a day.
- **Anxiety:** the usual dose is 80 mg to 160 mg a day.
- **Thyroid conditions (such as thyrotoxicosis):** the usual dose is 30 mg to 160 mg a day.
- **Phaeochromocytoma:** the usual dose is 30 mg to 60 mg 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 320 mg a day.

Use in children and adolescents

Under some conditions, Inderal can be used to treat children with arrhythmias (disorders of heart rhythm). The dosage will be adjusted by the doctor according to the child's age or weight.

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 tablets 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 first. In some cases, you may need to stop taking this medicine gradually.

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

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 (may affect up to 1 in 10 people)

- You may notice that your pulse rate becomes slower while you are taking the tablets. 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 (may affect up to 1 in 100 people)

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

Rare (may affect up to 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 (may affect up to 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.

Not known: frequency cannot be estimated from the available data

- Low levels of sugar in the blood. This can happen in people with or without diabetes. This includes newborn babies, toddlers, children, elderly people, people on artificial kidneys (haemodialysis), people who have taken too much Inderal, and people taking medicines for diabetes. It may also happen if you are fasting or in people with a long-term liver disease.
- Seizure linked to low levels of sugar in your blood.

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.

Reporting 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.

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5. How to store Inderal

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and bottle. The expiry date refers to the last day of that month.
- Do not store above 30°C. Protect your medicine from light and moisture. Store your tablets in the original package.
- Do not throw away any medicines via wastewater. 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 Inderal Tablets contain

The active substance is propranolol hydrochloride. Each tablet contains 10 mg of propranolol hydrochloride.

The other ingredients are lactose monohydrate, carmellose calcium, gelatin, magnesium stearate, hypromellose, glycerol (E422), titanium dioxide (E171), carmine (E120) and light magnesium carbonate.

What Inderal Tablets look like and contents of the pack

Inderal 10 mg Film-coated Tablets are pink and round with 'Inderal 10' on one side. The medicine comes in packs of 100 tablets.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for Inderal 10 mg Film-coated Tablets is held by AstraZeneca AB, SE-151 85 Södertälje, Sweden.

Inderal 10 mg Film-coated Tablets are manufactured by AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, UK.

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