

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Beta-Prograne 160mg & Half Beta-Prograne 80mg Prolonged-Release Capsules (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 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 Beta-Prograne and Half Beta-Prograne is and what it is used for
2. What you need to know before you take Beta-Prograne and Half Beta-Prograne
3. How to take Beta-Prograne and Half Beta-Prograne
4. Possible side effects
5. How to store Beta-Prograne and Half Beta-Prograne
6. Contents of the pack and other information

The name of this medicine is Beta-Prograne 160mg and Half Beta-Prograne 80mg Prolonged-Release Capsules (referred to as Beta-Prograne and Half Beta-Prograne throughout this leaflet).

1 What Beta-Prograne and Half Beta-Prograne is and what it is used for

Beta-Prograne and Half Beta-Prograne Capsules contain propranolol hydrochloride which belongs to a group of medicines called beta-blockers. Beta-blockers help slow the heart beat and relax the blood vessels. This reduces blood pressure and the heart's demand for oxygen.

Your doctor may have given you propranolol (the active ingredient) before but under a different brand name. The effect of Beta-Prograne or Half Beta-Prograne will be the same.

This medicine is used to treat the following:

- High blood pressure (hypertension).
- Pains in the chest (angina pectoris).
- Preventing migraines.
- Shaking of the hands, head and face (essential tremor).
- Anxiety.
- Overactive or enlarged thyroid (thyrotoxicosis).
- Bleeding in the stomach and intestines caused by high blood pressure in the liver.
- Protection against further heart attacks (if you have had already had one).

2 What you need to know before you take Beta-Prograne and Half Beta-Prograne

Do not take Beta-Prograne and Half Beta-Prograne if:

- you are allergic to propranolol (the active ingredient) or any of the other ingredients of this medicine (listed in section 6).
- **you have a history of breathing difficulties, wheezing or asthma. Ask your doctor or pharmacist if you should take this medicine.**
- you have any of the following heart problems:
 - slower heartbeat (bradycardia).
 - Second or third degree heart block.
 - irregular heartbeat (sick sinus syndrome).
 - weakened heart unable to pump blood around the body (cardiogenic shock).
 - heart failure, which is **uncontrolled**.
 - low blood pressure (hypotension).
 - severely restricted blood supply to the limbs (severe peripheral arterial circulatory disturbances).
 - chest pains when at rest (Prinzmetal's angina).

- You have an **untreated** tumour of the adrenal gland (phaeochromocytoma).
- you are prone to low blood sugar levels (hypoglycaemia) or you have not eaten for a long time (as the risk of low blood sugar levels is significantly increased).
- you have increased level of acid in your blood (metabolic acidosis).

Warnings and precautions

Talk to your doctor before taking Beta-Prograne and Half Beta-Prograne Capsules if:

- you have a reduced blood supply to the heart (ischaemic heart disease), you have **controlled** heart failure, your heart has difficulty pumping blood around your body (poor cardiac reserve), you have a slower heartbeat.
- you have poor circulation (conditions such as Raynaud's syndrome or intermittent claudication), as this medicine may aggravate it.
- you have a slow or irregular heartbeat (first degree heart block).
- you have a history of severe allergic reaction which can cause difficulty in breathing or dizziness (anaphylactic reaction).
- you have thyrotoxicosis or hyperthyroidism (a high level of thyroid hormones in the blood) as this medicine may mask the symptoms.
- You have a **treated** tumour of the adrenal gland (phaeochromocytoma).
- you are elderly, as you may need to start on a lower dose.
- you have any kidney or liver problems, including cirrhosis.
- you have diabetes as this medicine may block the signs and symptoms of low blood sugar levels (hypoglycaemia).

Other medicines and Beta-Prograne and Half Beta-Prograne

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal medicines.

Medicines which **may interact with or be affected by** Beta-Prograne and Half Beta-Prograne:

- Cimetidine, used to treat stomach ulcers.
- Fluvoxamine, imipramine used to treat depression.
- Rifampicin, an antibiotic used to treat infections, particularly tuberculosis.
- Thyroxine, used to treat thyroid disorders.
- Alcohol (see 'Taking Beta-Prograne and Half Beta-Prograne with Alcohol' section).
- Adrenaline, a heart stimulant (sympathomimetics).
- Medicines used to treat heart failure such as digoxin or digitoxin (digitalis glycosides).
- Ergotamine, dihydroergotamine or rizatriptan, used to treat migraine.
- Anti-inflammatory pain relievers such as ibuprofen and indomethacin, used to treat arthritis and similar conditions.
- Medicines used to treat irregular heartbeats, such as lidocaine, disopyramide, flecainide, amiodarone, quinidine and propafenone.
- ACE inhibitors and Angiotensin-II Antagonists, used to treat high blood pressure e.g. hydralazine prazosin.
- Calcium channel blockers such as verapamil, diltiazem, nifedipine, nisoldipine, isradipine, lacidipine, dihydropyridine, used to treat high blood pressure (hypertension) and chest pains (angina).
- Chlorpromazine, thioridazine used to treat mental disorders.
- Theophylline, used to treat asthma.
- Warfarin, used to thin the blood.
- Clonidine, used to treat high blood pressure and migraine.
- Medicines used to treat diabetes, such as insulin.

Having an anaesthetic or laboratory test

You must tell the medical staff that you are taking Beta-Prograne or Half Beta-Prograne if you are going to have surgery under anaesthetic or a laboratory test.

- **Anaesthetics** – Anaesthetics may interfere with this medicine and cause low blood pressure (hypotension).
- **Laboratory tests** – This medicine may interfere with the results obtained.

Taking Beta-Prograne and Half Beta-Prograne with Alcohol

It is recommended that you do not drink alcohol whilst being treated with Beta-Prograne or Half Beta-Prograne Capsules as it may affect how this medicine works.

Pregnancy and breast-feeding

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

Pregnancy

Beta-Prograne or Half Beta-Prograne should not be used in pregnancy unless absolutely necessary.

Breast-feeding

Breast-feeding is not recommended as this medicine passes into the breast-milk.

Driving or using machinery

Beta-Prograne and Half Beta-Prograne should not impair your ability to drive or operate machinery. However, you may feel dizzy or tired. If this occurs, do not drive or operate machinery.

This medicine contains sulfur dioxide (E220)

May rarely cause severe hypersensitivity (allergic) reactions and bronchospasm (difficulty in breathing or wheezing).

This medicine contains sucrose

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

3 How to take Beta-Prograne and Half Beta-Prograne

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

These capsules are for oral use and should be swallowed whole.

Adults

High blood pressure (hypertension):

- The usual starting dose is 160mg daily, taken in the morning or evening.
- Your doctor may decide to increase this dose.
- The maximum dose is 320mg daily.

Chest pain (angina), shaking (essential tremor), thyroid conditions (e.g. thyrotoxicosis), prevention of migraines:

- The usual dose is 80mg daily, taken in the morning or evening.
- The dose may be increased to 160mg.

Anxiety:

- The usual dose is 80mg daily.
- The dose may be increased to 160mg daily.

High blood pressure in the liver (portal hypertension):

- The usual starting dose is 80mg daily.
- The dose may be increased to 160mg daily.
- The maximum dose is 320mg daily.

After a heart attack (myocardial infarction):

- The initial starting dose is 40mg four times daily for 2 or 3 days.
- The total daily dosage thereafter may be given as a single 160mg capsule or two 80mg capsules daily.

Elderly

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

Use in children

Beta-Prograne 160mg and Half Beta-Prograne 80mg Capsules are not suitable for use in children.

If you take more Beta-Prograne or Half Beta-Prograne than you should

If you accidentally take too many capsules, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining capsules with you.

Symptoms of overdose may include: slower heartbeat (bradycardia, 1st - 3rd degree AV block), low blood pressure (hypotension), excess collection of watery fluid in the lungs (pulmonary oedema), fainting (syncope), weakened heart unable to pump blood around the body (cardiogenic shock), faster heartbeat (tachycardia), life-threatening irregular heartbeat (ventricular fibrillation), cardiac flatline (asystole), drowsiness, confusion, seizures, seeing or hearing things that are not real (hallucinations), dilated pupils of the eyes, difficulty in breathing or wheezing (bronchospasm), abnormally high levels of potassium in blood (hyperkalaemia) and in severe cases, coma may occur. Occasionally respiratory depression (breathing more slowly or weakly than usual) may occur.

If you forget to take Beta-Prograne or Half Beta-Prograne

Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, **do not** take a double dose to make up for a forgotten dose.

Do not stop taking Beta-Prograne or Half Beta-Prograne

It is important that you keep taking this medicine for as long as your doctor has told you to.

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

4 Possible side effects

Like all medicines, Beta-Prograne or Half Beta-Prograne can cause side effects, although not everybody gets them.

Seek medical advice immediately if you develop the following symptoms:

- Allergic reactions: swelling of the face, throat or tongue
- Difficulty in breathing or wheezing (bronchospasm), particularly if you have asthma or a history of asthma

Common side effects (may affect up to 1 in 10 people)

- Feeling tired (often short-term)
- Slower heartbeat (bradycardia)
- Cold hands and feet
- Poor circulation causing fingers & toes to be pale and numb (Raynaud's syndrome)
- Disturbed sleep or nightmares

Uncommon side effects (may affect up to 1 in 100 people)

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

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

- Dizziness
- A reduction in blood platelets, which increases the risk of bleeding or bruising (thrombocytopenia)
- Worsening of heart failure
- Start of heart block, which may cause an abnormal heartbeat, dizziness, tiredness or fainting
- Low blood pressure when changing position (postural hypotension), which may cause fainting (syncope)

- Worsening of cramp-like pain felt in the calf, thigh or buttock during walking or other exercise (intermittent claudication)
- Seeing or hearing things that are not real (hallucinations)
- Mental illness (psychosis)
- Mood changes
- Confusion
- Memory loss
- Skin rash caused by small blood vessels bleeding into the skin (purpura)
- Hair loss (alopecia)
- Skin disease causing scaly pink patches (psoriasis) or worsening of the condition
- Skin rashes
- Tingling or numbness in the hands or feet (paraesthesia)
- Dry eyes
- Disturbances of vision

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

- Increase in ANA (Antinuclear Antibodies – detected through blood test)
- Muscle weakness or worsening of the condition (myasthenia gravis)

Other side effects (frequency not known)

- More prone to infections due to a severe reduction in number of white blood cells (agranulocytosis)
- Changes to fat levels in blood
- Low blood sugar levels (hypoglycaemia), including seizure linked to hypoglycaemia
- Depression
- Confusion
- Headache
- Infection that causes inflammation of the eye, red eyes, itchiness and discharge (conjunctivitis)
- Worsening of angina (chest pain)
- Shortness of breath or difficulty in breathing (dyspnoea)
- Constipation
- Dry mouth
- Pain or swelling in the joints (arthralgia)
- Changes in kidney function
- Sexual disorders

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 via HPRC Pharmacovigilance, website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Beta-Prograne and Half Beta-Prograne

- Keep this medicine out of the sight and reach of children.
- Do not use Beta-Prograne and Half Beta-Prograne after the expiry date, which is stated on the carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6 Contents of the pack and other information

What Beta-Prograne and Half Beta-Prograne contain:

- Each Beta-Prograne capsule contains 160mg propranolol hydrochloride.
- Each Half Beta-Prograne capsule contains 80mg propranolol hydrochloride.

The other ingredients are: neutral microgranules (maize starch, sucrose), povidone, ethylcellulose, talc, gelatin, titanium dioxide (E171) and sulfur dioxide (E220).

What Beta-Prograne and Half Beta-Prograne look like and the contents of the pack:

- Beta-Prograne 160mg are white opaque, size 2, hard gelatin capsules containing white microgranules.
- Half Beta-Prograne 80mg are transparent, hard gelatin capsules with a white cap, containing white microgranules.

Beta-Prograne and Half Beta-Prograne are available in:

Beta-Prograne and Half Beta-Prograne are available in blister packs of 28 capsules.

Product Licence Numbers:

- Beta-Prograne 160mg PR Capsules: PA 22720/002/001
- Half Beta-Prograne 80mg PR Capsules: PA 22720/002/002

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