

Half Beta-Prograne 80mg Prolonged-Release Capsules

(propranolol hydrochloride)

Patient Information Leaflet

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, please ask your doctor or your 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. This includes any possible side effects not listed in this leaflet. (See Section 4).

What is in this leaflet:

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

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

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

Half Beta-Prograne Capsules belong to a group of medicines called beta-blockers, which 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 substance) before but under a different brand name. The effect of Half Beta-Prograne Capsules (propranolol hydrochloride) will be the same.

This medicine is used to treat the following conditions:

- * High blood pressure (hypertension).
- * Pains in the chest (angina).
- * Shaking of the hands, head and face (essential tremor).
- * Anxiety symptoms.
- * Overactive or enlarged thyroid (thyrotoxicosis or graves' disease).
- * Preventing migraines.
- * Bleeding in the stomach and intestines caused by high blood pressure in the belly region and lower throat.
- * Protecting the heart after a heart attack

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

Do not take Half Beta-Prograne Capsules if:

- * you are allergic (hypersensitive) to propranolol or any of the other ingredients in the capsules (see Section 6, Contents of the pack and other information).
- * **you have a history of breathing difficulties, wheezing or asthma. Ask your doctor or pharmacist if you should take this medicine.**
- * 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 (may be treated with a pacemaker).
 - very slow heart rate and uneven beats
 - low blood pressure
 - severe circulation problems
 - chest pains when at rest (Prinzmetal's angina).
- * you are prone to having a lack of glucose in the bloodstream (hypoglycaemia). This is more likely if you have not eaten for a long time, you have a poor diet, chronic liver disease, diabetes or you are taking certain medicines.
- * you have more acid than normal in your blood (metabolic acidosis).
- * you have an untreated tumour in inner part of the adrenal gland (phaeochromocytoma).

Warnings and precautions

- * Talk to your doctor before taking Half Beta-Prograne Capsules if:
- * your heart has difficulty pumping blood around your body (low cardiac reserve), you have controlled heart failure or a slow heart beat.
- * you have poor blood circulation.
- * you have diabetes. This medicine may block the signs and symptoms of low blood sugar levels (hypoglycaemia).
- * you have an irregular heart beat (first degree heart block).
- * you have any kidney or liver problems.
- * you have a history of severe allergic reaction which can cause difficulty in breathing or dizziness (anaphylactic reaction).
- * you have thyrotoxicosis (a condition caused by an overactive thyroid gland). Your medicine may mask the symptoms of thyrotoxicosis.
- * you are elderly, as you may need to start on a lower dose.

If any of the conditions listed under 'Do not take' or 'Warnings and precautions' apply to you, please contact your doctor or pharmacist.

Other medicines and Half Beta-Prograne

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription. This is because some medicines may affect the way Half Beta-Prograne Capsules work and some medicines can have an effect on this medicine. In particular, tell your doctor if you are taking any of the following:

- * Cimetidine, for stomach ulcers and indigestion.
 - * Rifampicin, antibiotic used for various infections, in particular tuberculosis.
 - * Alcohol (see heading below Half Beta-Prograne with Alcohol).
 - * Adrenaline or noradrenaline, for emergency treatment of an allergic reaction (anaphylaxis) or if the heart stops (cardiac arrest).
 - * Amphetamines, for tiredness, phenylephrine*, used in eye drop solutions and phenylpropanolamine*, for the relief of cold symptoms (*widely used in medicines purchased over the counter). Other sympathomimetic amines drugs such as salbutamol and isoprenaline, for asthma.
 - * Medicines for heart failure such as digoxin (digitalis glycosides).
 - * Ergotamine, dihydroergotamine or rizatriptan, for migraine.
 - * Indomethacin, for arthritis and other prostaglandin inhibiting drugs for pain and inflammation, such as ibuprofen.
 - * Medicines for irregular heart beat, such as lignocaine, lidocaine, disopyramide, amiodarone, procainamide, quinidine and propafenone.
 - * Nifedipine, nisoldipine, nicardipine, isradipine and lacidipine, for high blood pressure and chest pains (hypertension and angina).
 - * Other medicines for high blood pressure such as guanethidine, reserpine, diuretics, such as water tablets and vasodilators, such as diazoxide.
 - * Chlorpromazine for anxiety, feeling sick (nausea), being sick (vomiting) or mental disorders and other phenothiazines, such as thioridazine.
 - * Theophylline used to treat asthma.
 - * Warfarin used to thin the blood.
 - * Clonidine, for high blood pressure and migraine.
- If you are taking clonidine and Half Beta-Prograne Capsules 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.
- * Verapamil or diltiazem, medicines for high blood pressure or chest pains (angina).
 - * Medicines for the treatment of diabetes, such as insulin and metformin.

Having an anaesthetic or laboratory test

You must tell the medical staff that you are taking Half Beta-Prograne Capsules 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.

Half Beta-Prograne with Alcohol

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

Pregnancy and breast-feeding

If you are pregnant or thinking of becoming pregnant, you should not take this medicine, unless considered essential by your doctor.

If you are breast-feeding you should not take this medicine.

Driving and using machines

Half Beta-Prograne Capsules are unlikely to affect your ability to drive or operate machinery. Occasionally you may feel a bit dizzy or more tired than normal. If this happens, do not drive or operate machinery and consult your doctor or pharmacist.

Important Information about the ingredients

These capsules contain the ingredient **sulphur dioxide**, which on rare occasions, may cause severe allergic reactions and difficulty in breathing or wheezing.

These capsules contain **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 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 to be swallowed whole with a glass of water, do not open or chew the capsules.
- * Each capsule should be taken at a regular time each day (morning or evening), unless instructed differently.

Warning for diabetics

Diabetics should not go for long periods without food whilst taking Half Beta-Prograne Capsules. Ask your doctor for advice if you have missed several meals for any reason.

One of the actions of this medicine is to slow the heart. This could mask an increase in the heart rate which may be a warning sign of low blood sugar levels (hypoglycaemia). In addition, it may delay the recovery of blood glucose to normal levels after taking insulin.

Half Beta-Prograne 80mg Prolonged-Release Capsules

(propranolol hydrochloride)

Patient Information Leaflet (continued)

Adults

The doses stated below are guidelines only. You should always take this medicine as prescribed by your doctor.

The usual daily dosages for an adult are:

High blood pressure (hypertension): the usual dose is 160 mg a day. Your doctor may decide to increase this dose.

Chest pain (angina): the usual dose is 80 mg to 240 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 240 mg a day.

Essential tremor: the usual dose is 80 mg to 240 mg a day.

Anxiety: the usual dose is 80 mg to 240 mg a day.

Thyroid conditions (such as thyrotoxicosis): the usual dose is 80 mg to 240 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.

Elderly people

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

Children

Half Beta-Prograne 80mg Capsules should not be given to children.

If you forget to take your Half Beta-Prograne Capsules

Continue with the normal dose 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 the dose you have missed.

If you have taken more Half Beta-Prograne Capsules than recommended

You should immediately call your doctor or go to the nearest hospital casualty department. Take with you any remaining medicine, the original carton and the label so that the medicine can be identified.

Do not stop taking Half Beta-Prograne Capsules without your doctor's advice

It could be dangerous. Continue to take this medicine for as long as the doctor has told you to. Your doctor will gradually reduce your dose before you stop taking this medicine.

4 Possible side effects

Half Beta-Prograne Capsules are usually well tolerated. However like all medicines they can cause side effects in some patients, particularly when treatment is first started.

Contact your doctor immediately if you have the following symptoms:

- * Slow heart beat and low blood pressure causing dizziness, light-headedness, fainting or blurred vision
These may be symptoms of intolerance to the medicine
- * Difficulty in breathing. This is more likely if you have asthma or a history of asthmatic problems

Common side effects (affects less than 1 in 10 people)

- * Feeling tired (often transient)
- * Slow heart rate
- * Cold hands and feet
- * Poor blood circulation which makes the toes and fingers numb and pale (Raynaud's syndrome)
- * Disturbed sleep or nightmares

Uncommon side effects (affects less than 1 in 100 people)

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

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

- * Dizziness
- * Reduction in blood platelets, which increases the risk of bleeding or bruising
- * Worsening of heart failure, which can cause shortness of breath or ankle swelling
- * Start of heart block, which may cause an abnormal heart beat, dizziness, tiredness or fainting
- * Low blood pressure especially when going from sitting or lying position to standing up, which may cause light-headedness, fainting or dizziness
- * Worsening of pain and/or cramping in the lower leg (intermittent claudication)
- * Seeing or hearing things that are not real (hallucinations or psychosis)
- * Mood changes
- * Confusion
- * Purplish marks on your skin
- * Hair loss
- * Common skin condition known as psoriasis which causes scaly pink patches or worsening of the condition
- * Skin rashes

- * Tingling or numbness in the hands or feet
- * Dry eyes
- * Disturbances of vision

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

- * Low levels of sugar in the blood (hypoglycaemia). This can happen in people with or without diabetes. This includes infants, children, 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 long-term liver disease
- * Increase in ANA (Antinuclear Antibodies – detected through blood test)
- * Severe muscle weakness or worsening of the condition (myasthenia gravis)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 also provide more information on the safety of this medicine.

IRELAND: FREEPOST, Pharmacovigilance Section, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland. Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.imb.ie, e-mail: imbpharmacovigilance@imb.ie.

5 How to store Half Beta-Prograne

Keep out of sight and reach of children.

Store below 25°C. Store in the original package in order to protect from light and moisture.

Do not use Half Beta-Prograne Capsules 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 throw away any medicines 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 Half Beta-Prograne Capsules contain:

- * Active substance: 80mg propranolol hydrochloride.
- * Other ingredients: neutral microgranules, povidone, ethylcellulose, talc, gelatine, titanium dioxide (E171) and sulphur dioxide (E220).
(See 'Important information about the ingredients' section 2)

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

Half Beta-Prograne 80mg Prolonged Release Capsules:
Transparent gelatin capsules with a white cap, containing white microgranules.

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

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Manufactured by:

Tillomed Laboratories Ltd., 3 Howard Road, Eaton Socon, St. Neots, Cambridgeshire, PE19 8ET UK.

POM

PPA1097/018/001 Half Beta-Prograne Capsules

Revision date: 10/04/2017

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Phone Lexon (UK) Limited, Tel: +44 (0)1527 505414 for help.