

PACKAGE LEAFLET

Package leaflet: Information for the user

Prestim 10 mg/2.5 mg tablets timolol maleate and bendroflumethiazide

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.

What is in this leaflet:

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

1. WHAT PRESTIM TABLETS ARE AND WHAT IT IS USED FOR

Prestim tablets contain the active ingredients timolol, which belongs to a group of medicines called beta-blockers, and bendroflumethiazide, which belongs to a group of medicines called diuretics.

Prestim tablets are used for the management of mild to moderate hypertension (high blood pressure).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PRESTIM TABLETS

Do not take Prestim tablets:

- If you have a history of breathing problems such as bronchospasm, bronchial asthma, or chronic obstructive pulmonary disease (COPD)
- If you cannot pass urine
- If you have kidney failure or liver problems
- If you have Addison's disease (causes tiredness and muscle weakness)
- If you have a suddenly weakened heart
- If you have heart block, heart failure, or a very slow or very fast heart rate
- If you have sick sinus syndrome (a heart rhythm disorder)
- If you have bradycardia (a slow heart rate)
- If you have severe peripheral arterial disease (build-up of plaque in the arteries)
- If you have had an injection of verapamil (used to lower blood pressure) within the last 48 hours
- If you are taking lithium (a treatment for mental illness)
- If you have a tumour of the adrenal gland that is not being treated
- If you are going to have an anaesthetic
- If you have been told that you have metabolic acidosis (altered blood chemistry) or a low potassium level (hypokalaemia)
- If you have high uric acid levels in your blood which may cause gout
- If you have low blood pressure or problems with your blood circulation
- If you are suffering from digitalis (a heart stimulant) poisoning
- If you are allergic to timolol, bendroflumethiazide, or any of the other ingredients of this medicine or medicines known as a thiazide diuretic (listed in section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.

Warnings and precautions

Talk to your doctor or pharmacist before taking Prestim tablets if you have any of the following conditions:

- If you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking Prestim tablets. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.
- Have uncontrolled heart failure, a very slow heart rate, other heart problems or a certain type of angina called Prinzmetal's angina.
- Kidney or liver disease
- Diabetes, low blood sugar levels (hypoglycaemia)
- Slow heart rate
- Overactive thyroid gland
- A history of psoriasis (a skin condition)
- Gout or systemic lupus erythematosus (an allergic condition which may cause joint pain, skin rashes and fever)
- Have portal hypertension (high blood pressure in the blood vessel to your liver)
- Have higher than normal potassium or sodium levels in your blood or lower than normal calcium levels in your blood even with treatment
- Have protein in your urine
- Have a hormone condition called 'hyperaldosteronism'
- Are malnourished
- Have muscle weakness (myasthenia gravis)
- Have peripheral circulatory disorders (Raynaud's syndrome),
- You have angina (chest pain)
- You develop dry eyes or a rash
- You are elderly

You will be monitored to check your fluid balance and salts.

Children

There is no information on the use of Prestim tablets in children.

Other medicines and Prestim tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you take these tablets with some other medicines, the effect of these tablets or the other medicine may be changed. Tell your doctor or pharmacist if you are taking:

- Any other medicines for high blood pressure or heart problems such as: lignocaine, verapamil, disopyramide, tocainide, diltiazem, quinidine, amiodarone, clonidine, digitalis glycosides, reserpine, hydralazine, guanethidine, dihydropyridine derivatives (e.g. nifedipine) and any of the medicines known as class I antiarrhythmic agents.
- Medicines used for treating depression (e.g. lithium, tricyclic antidepressants and monoamine oxidase inhibitors) or other mental problems (e.g. phenothiazines).
- Medicines known as barbiturates, used to treat sleeping disorders.
- Dihydropyridine derivatives such as nifedipine
- An anti-ulcer medicine called cimetidine.
- An antibiotic called rifampicin.
- Medicines known as prostaglandin synthetase inhibitors (e.g. ibuprofen, aspirin)
- Medicines known as sympathomimetic agents used for asthma (e.g. salbutamol), to stimulate your heart (e.g. isoprenaline) and in some cough and cold preparations.
- Medicines for treating diabetes (e.g. insulin or oral anti-diabetic medicines).
- Medicines that work by reducing the amount of important chemicals; adrenaline and catecholamines, that are involved in nerve function (e.g. reserpine).
- Medicines that increase the QT interval (e.g. astemizole, terfenadine, halofantrine, pimozone, sotalol)

- Medicines that may cause hypokalaemia (low potassium levels) such as steroids and theophylline
- Medicines that cause fluid retention such as corticosteroids, NSAIDs, or carbenoxolone

It may still be all right for you to be given Prestim tablets and your doctor will be able to decide what is suitable for you.

If you are going to have surgery

If you are going to have an operation in hospital or going to the dentist, tell the doctor at the hospital or the dentist that you are taking Prestim Tablets.

Certain anaesthetics should not be used with these tablets (e.g. ether, cyclopropane, trichloroethylene). You should not be given a local anaesthetic combined with adrenaline while you are taking Prestim Tablets.

Pregnancy and breast-feeding

You should not take Prestim tablets while pregnant or breast-feeding as it may harm the baby.

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 using machines

Prestim may cause dizziness or tiredness. If you are affected, you should not drive or operate machinery.

3. HOW TO TAKE PRESTIM TABLETS

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

Adults:

The usual dose can vary from 1 to 4 tablets.

You can take the tablets as a single dose in the morning or in two doses, one in the morning and the other in the evening.

Elderly:

Treatment will start with 1 tablet daily.

Your doctor will adjust your dose as necessary.

Patients with liver or kidney impairment:

Your doctor will decide the correct dose.

If you have severe liver or kidney problems, you should not take Prestim Tablets.

Method of administration:

Prestim Tablets should be swallowed whole with water.

If you take more Prestim tablets than you should

Go to the accident and emergency department of your hospital immediately. Signs of overdose are slow heartbeat, dizziness, asthma-like symptoms and difficulty breathing.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions are very rare.

Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body)

The following side effects have been reported:

- Decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma)
- Upset stomach, vomiting, nausea, diarrhoea
- Inflammation of the pancreas, which causes severe pain in the abdomen and back (acute pancreatitis)
- Headache, dizziness, tiredness, depression, weakness, sleeplessness, breathing difficulties, vertigo, sedation, disorientation, insomnia, hallucination, nightmare, confusional state, coma (state of unconsciousness in which a person cannot be awakened)
- A slow heartbeat, low blood pressure, worsening heart failure or heart problems
- You may also experience tired or painful muscles; feel thirsty and pass less urine than normal (dehydration)
- If you are short sighted this may get worse; blurred vision, dry eye
- An increase in blood sugar and sugar in the urine (particularly in people who are diabetic), oliguria (decreased urine production), changes in levels of some substances in the blood (hyperuricaemia) often associated with gout
- Blood disease, inflammation of blood vessels (necrotizing vasculitis), changed blood cells (may lead to unexplained bruising or bleeding; sore throat, fever or infection; pale skin, tiredness or breathlessness)
- Erectile dysfunction
- Raynaud's syndrome, peripheral coldness (cold extremities)
- Allergic dermatitis, rash, photosensitivity reactions (skin sensitivity to light),
- Retroperitoneal fibrosis (a rare disorder in which the tubes (ureters) that carry urine from the kidneys to the bladder are blocked)
- Withdrawal syndrome (abrupt withdrawal may precipitate angina in susceptible patients or cause rebound hypertension)
- High level of calcium in the blood

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 via HPRA 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 PRESTIM TABLETS

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 original container after "EXP". The expiry date refers to the last day of that month.

Store the tablets below 25 °C.

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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Prestim tablets contain

Each tablet capsule contains 10 mg of the active ingredient timolol maleate and 2.5 mg of the active ingredient bendroflumethiazide.

The other ingredients are: microcrystalline cellulose, maize and starch and magnesium stearate.

What Prestim tablets look like and contents of the pack

Prestim are white, oval shaped tablets with a single score line on one face and engraved on the other side with "V PRE"

Prestim tablet come in amber glass bottles containing 30 or 100 tablets.

Not all pack sizes may be marked.

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