

Patient Information Leaflet**Timolol maleate/Bendroflumethiazide 10 mg/2.5 mg tablets****10 mg timolol maleate****2.5 mg bendroflumethiazide****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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

In this leaflet:

1. What Timolol maleate/Bendroflumethiazide is and what it is used for
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1. WHAT TIMOLOL MALEATE/BENDROFLUMETHIAZIDE IS AND WHAT IT IS USED FOR

Timolol maleate/Bendroflumethiazide 10 mg/2.5 mg tablets are a combination of two medicines; one slows your heart rate and the other increases water removal from your body.

Timolol maleate/Bendroflumethiazide 10 mg/2.5 mg tablets are used to treat raised blood pressure. Your doctor has prescribed these tablets for you because your blood pressure is too high.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TIMOLOL MALEATE/BENDROFLUMETHIAZIDE 10 MG/2.5 MG TABLETS

Do not take Timolol maleate/Bendroflumethiazide 10 mg/2.5 mg tablets if you:

- Are allergic (hypersensitive) to timolol maleate, bendroflumethiazide, any of the other ingredients of Timolol maleate/Bendroflumethiazide (these are listed in section 6, "Contents of the pack and other information"), or any medicine known as a thiazide diuretic.
- Have bronchial asthma or a chronic lung disease.
- Have a history of wheezing or asthma.
- Have serious kidney or liver problems.
- Have difficulty urinating.
- Have lower than normal potassium or sodium levels in your blood or higher than normal calcium levels in your blood even with treatment.
- Have high uric acid levels in your blood which may cause gout.
- Have chronic adrenal insufficiency (Addison's disease).
- Have uncontrolled heart failure, a very slow heart rate, other heart problems or a certain type of angina called Prinzmetal's angina.
- Have low blood pressure or problems with your blood circulation.
- Have a condition affecting your adrenal glands called pheochromocytoma.

- Have a condition that causes acidity of the blood called metabolic acidosis.
- Are taking medicines used for relieving depression such as lithium, monoamine oxidase inhibitors (e.g. selegiline, moclobedine) and tricyclic antidepressants (e.g. amitriptyline, lofepramine).
- Are pregnant, or think that you might be pregnant.

Warnings and Precautions

Tell your doctor before you start treatment if you have or have had in the past one of the following problems or if you develop any of these during treatment:

- Suffer from diabetes, low blood sugar levels (hypoglycaemia), heart, liver or kidney problems.
- 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 swelling in your ankles, hands or eye area.
- Have non-serious kidney problems (see “Do not take Timolol maleate/Bendroflumethiazide” section above if you have serious kidney problems).
- Have a hormone condition called ‘hyperaldosteronism’.
- Are malnourished.
- Have muscle weakness (myasthenia gravis).
- Suffer from an overactive thyroid gland.
- Suffer from gout or systemic lupus erythematosus (an allergic condition which can cause joint pain, skin rashes and fever).
- Psoriasis (this is a skin disease with thickened patches of red skin, often with silvery scales).
- 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 a week of taking Timolol maleate/Bendroflumethiazide 10 mg/2.5 mg 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.

Children

Timolol maleate/Bendroflumethiazide 10 mg/2.5 mg tablets are not suitable for children.

Other medicines and Timolol maleate/Bendroflumethiazide 10 mg/2.5 mg tablets

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

This is extremely important, as using more than one medicine at the same time can strengthen or weaken the effect of the medicines. In particular, tell your doctor if you are taking any of the following:

- Any other medicines for high blood pressure or heart problems such as: lignocaine, verapamil, disopyramide, tocainide, diltiazem, quinidine, amiodarone, clonidine, digitalis glycosides, hydralazine, dihydropyridine derivatives (e.g. nifedipine) and any of the medicines known as class I antiarrhythmic agents.
- Any medicines which increase the QT interval of the heart such as astemizole, terfenadine, halofantrine, pimozone and sotalol.
- 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.
- An anti-ulcer medicine called cimetidine.
- An antibiotic called rifampicin and also tetracyclines.
- Medicines known as prostaglandin synthetase inhibitors (e.g. ibuprofen, aspirin).

- Any steroid medicines.
- Theophylline.
- 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).

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 Timolol maleate/Bendroflumethiazide 10 mg/2.5 mg 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 Timolol maleate/Bendroflumethiazide 10 mg/2.5 mg tablets.

Taking Timolol maleate/Bendroflumethiazide 10 mg/2.5 mg tablets with food and drink

You should avoid excessive alcohol consumption while taking Timolol maleate/Bendroflumethiazide.

Pregnancy and breast-feeding

Tell your doctor before you take any tablets if you are pregnant or breast-feeding. Also, tell your doctor if you become pregnant during treatment.

Do not take Timolol maleate/Bendroflumethiazide 10 mg/2.5 mg tablets if you are pregnant. Your doctor will decide if you should take Timolol maleate/Bendroflumethiazide while you are breast-feeding.

Driving and using machines

This medicine may cause tiredness or dizziness as a side effect. Therefore you should be careful if you are going to drive or operate machinery.

3. HOW TO TAKE TIMOLOL MALEATE/BENDROFLUMETHIAZIDE 10 MG/2.5 MG TABLETS

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

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.

Timolol maleate/Bendroflumethiazide 10 mg/2.5 mg tablets should be swallowed whole with water.

If you take more Timolol maleate/Bendroflumethiazide 10 mg/2.5 mg tablets than you should

If you or anyone else accidentally take more than the recommended dose of these tablets, call your doctor straight away or go to your nearest hospital casualty department.

If you forget to take Timolol maleate/Bendroflumethiazide

If you forget to take your tablet(s), take the next dose as normal. Do not take a double dose to make up for forgotten tablet(s).

If you stop taking Timolol maleate/Bendroflumethiazide

Keep taking the Timolol maleate/Bendroflumethiazide 10 mg/2.5 mg tablets for as long as your doctor tells you to. Do not stop taking them without consulting your doctor first. If it is right for you to stop taking Timolol maleate/Bendroflumethiazide then your doctor will probably reduce the dose gradually since it is important not to stop suddenly. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Timolol maleate/Bendroflumethiazide can cause side effects, although not everybody gets them.

Tell your doctor immediately if you experience severe abdominal pain and vomiting or you notice inflammation of your blood vessels (e.g. veins) accompanied by small red or purple, solid, and raised skin lesions on your legs, hands, or other parts of the body, and/or blue fingers or toes.

Tell your doctor if you notice a skin rash, visual disturbances, or dry eyes. Your doctor may decide to change your treatment. If you have a skin rash, this may be associated with an increased sensitivity to sunlight.

Tell your doctor if you have any of the side effects mentioned below and you are concerned:

- Upset stomach, dizziness, tiredness, depression, weakness, sleeplessness, breathing difficulties, a slow heart beat or other heart problems.
- You may also experience tired or painful muscles, feel thirsty and pass less urine than normal.
- If you are short sighted this may get worse.
- Poor blood circulation which makes your toes and fingers numb and pale, low blood pressure, “pins and needles”, tingling in the hands or feet, a worsening of any problems with blood circulation in your legs or impotence (male erection problems).
- Painful joints.
- Nausea (feeling sick), vomiting (being sick), diarrhoea or abdominal pain.
- Vertigo or feeling faint, headaches, trouble with sleeping or nightmares.
- Depression, hallucinations, drowsiness, disorientation, confusion or other mental problems.
- High level of calcium in the blood
- 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).

Some side effects will not normally be noticed. These include an increase in blood sugar and sugar in the urine (particularly in people who are diabetic), changes in levels of some substances in the blood, such as a decrease in potassium or an increase in urea, and changed blood cells. Your doctor may therefore need to do some tests.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TIMOLOL MALEATE/BENDROFLUMETHIAZIDE 10 MG/2.5 MG TABLETS

Keep out of the sight and reach of children.

Store Timolol maleate/Bendroflumethiazide 10 mg/2.5 mg tablets below 25 °C.

Do not use Timolol maleate/Bendroflumethiazide after the expiry date which is stated on the

bottle label and outer carton after the text “EXP“. The expiry date refers to the last day of that month.

Medicines must not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Timolol maleate/Bendroflumethiazide contains

Active substance: Timolol maleate and bendroflumethiazide.
Each tablet contains 10 mg of timolol maleate and 2.5 mg of bendroflumethiazide.

Other ingredients: Microcrystalline cellulose, pregelatinised starch and magnesium stearate.

What Timolol maleate/Bendroflumethiazide looks like and contents of the pack

Timolol maleate/Bendroflumethiazide 10 mg/2.5 mg tablets are white, flat and oval with “V PRE” imprinted on one side and a break-mark on the other.

The tablets are supplied in glass bottles of 30, 100 or 500 tablets.

Not all packs sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire,
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Manufacturer

Labiana Pharmaceuticals S.L.U., Casanova 27 – 31,
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For any information about this medicine, please contact the Marketing Authorisation Holder.

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If this leaflet is difficult to see or read, or you would like it in a different format, please contact Mylan, Potters Bar, Hertfordshire, EN6 1TL, UK.