

PATIENT INFORMATION LEAFLET
Timolol maleate 10 mg tablets

Timolol maleate

Please read all of this leaflet carefully before you start taking this medicine because it contains important 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. 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 is and what it is used for
2. What you need to know before you take Timolol maleate 10 mg tablets
3. How to take Timolol maleate 10 mg tablets
4. Possible side effects
5. How to store Timolol maleate 10 mg tablets
6. Contents of the pack and other information

1. WHAT TIMOLOL MALEATE IS AND WHAT IT IS USED FOR

Timolol maleate 10 mg tablets are used to treat high blood pressure (hypertension) and chest pain (angina). The tablets are also used to prevent a heart attack in those people who have already had one and in reducing the number of migraine attacks for those who suffer from migraine.

Timolol maleate 10 mg tablets belong to a group of medicines called beta-blockers which slow the heart rate and lower blood pressure, reducing the workload on the heart.

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

Do not take Timolol maleate if you :

- Are allergic to Timolol maleate or any of the other ingredients of Timolol maleate (these are listed in section 6, "Contents of the pack and other information").
- Have a history of wheezing or asthma.
- Have chronic (long-term) breathing difficulties.
- Have a certain type of chest pain called Prinzmetal's angina.
- Have uncontrolled heart failure.
- Have been told that you have a slower than normal heart beat or a severe heart condition called cardiogenic shock.
- Have any problems with your blood circulation.
- Are taking medicines known as monoamine oxidase inhibitors that are used for depression.
- Have a condition affecting your adrenal glands called pheochromocytoma.
- Have a condition that causes acidity of the blood called metabolic acidosis.
- Have low blood pressure.

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:

- Any heart problems at all, including an abnormally slow heart rate or coronary heart disease.
- Liver or kidney problems.
- Lung diseases (e.g. COPD)
- Diabetes or low blood sugar levels. Timolol maleate may mask some of the usual signs that your blood sugar level is too low.

If you are on medication for diabetes, Timolol maleate could also increase the effectiveness of insulin or oral anti-diabetic drugs so your dose of these may need to be changed.

- Disease of the cornea (eye)
- Have recently or will soon undergo surgery.
- The skin condition psoriasis.
- Poor circulation in your legs or arms.
- Any allergies (e.g. to pollen), as Timolol maleate may intensify your allergic reaction.

It is important to discuss these with your doctor because you may need to stop your treatment or have your dose changed.

Children

Timolol maleate 10 mg tablets are not suitable for children.

Other medicines and Timolol maleate

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is very important because you should not use some other medicines while you are taking Timolol maleate.

Also, certain other medicines can be used only if special precautions are taken.

In particular, tell your doctor or pharmacist if you are taking:

- Any medicines for high blood pressure (e.g. clonidine or hydralazine).
- Other medicines for heart problems (e.g. verapamil, disopyramide, lignocaine, tocainide, diltiazem, quinidine, amiodarone, nifedipine, digitalis glycosides (e.g. digoxin), or any of the medicines known as class I antiarrhythmic agents).
- Other beta-blockers.
- Medicines known as tricyclic antidepressants used for treating depression, or medicines known as phenothiazines used for treating other mental problems.
- Medicines known as barbiturates used to treat sleeping disorders.
- Medicines for treating diabetes (e.g. insulin and oral anti-diabetic drugs).
- An anti-ulcer drug called cimetidine.
- An antibiotic called rifampicin.
- Medicines to improve circulation.
- Medicines for breathing difficulties (e.g. salbutamol or isoprenaline).
- Medicines for migraine known as ergot preparations.
- Medicines known as prostaglandin synthetase inhibitors (e.g. ibuprofen, aspirin, indomethacin).
- Medicines known as CYP2D6 inhibitors (e.g. quinidine, fluoxetine, paroxetine).

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 10 mg tablets. Your doctor may decide to stop Timolol maleate gradually before you have an anaesthetic such as ether, cyclopropane, trichloroethylene. You should not be given a local anaesthetic combined with adrenaline while you are taking Timolol maleate.

Taking Timolol maleate with food and drink

You should avoid excessive alcohol consumption while taking Timolol maleate.

Pregnancy and breast-feeding

You should not take Timolol maleate if you are pregnant unless necessary.

Therefore, tell your doctor before you start treatment if you are pregnant, think that you may be pregnant or intend to become pregnant.

Consult with your doctor immediately if you think that you have become pregnant during treatment with Timolol maleate.

Tell your doctor before you start treatment with Timolol maleate if you are breast-feeding or planning to breastfeed.

Breast feeding is not recommended whilst taking Timolol maleate.

Driving and using machines

This medicine may cause tiredness, dizziness or visual disturbances as a side effect.

Therefore you should be careful if you are going to drive or operate machinery.

3. HOW TO TAKE TIMOLOL MALEATE 10 MG TABLETS

Your doctor will work out the right number of tablets for you. Always take Timolol maleate exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.



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Swallow the tablet(s) with a glass of water.

The usual dose for adults is:

- Half a tablet to three tablets twice a day for chest pains.
- One to six tablets a day for high blood pressure.
- Half a tablet to one tablet twice a day after a heart attack.
- One to two tablets a day to prevent migraine attacks.

The tablet can be divided into equal doses.

If you are elderly the doctor will probably start with the lowest adult dose and then adjust your dose carefully, depending on how you respond to treatment.

Timolol maleate 10 mg tablets are not suitable for children.

Your doctor may change the number of tablets you take. This will depend on how well you respond to the treatment. Do not alter the number of tablets you are taking without checking with your doctor.

If you take more Timolol maleate than you should
If you or anybody else accidentally take more than the recommended dose of these tablets, call your doctor immediately or go to your nearest hospital casualty department.

If you forget to take Timolol maleate
If you forget to take your tablet(s), take the next dose as normal.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Timolol maleate
Do not stop taking the tablets without first consulting your doctor.

If it is right for you to stop taking the medicine 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 can cause side effects, although not everybody gets them.

Serious side effects

Stop taking this medicine and seek urgent medical advice immediately if you have any of the following serious side effects:

- Breathing difficulties or a worsening of asthma.
- Irregular or slow heart beat or the heart slows so much that you faint, chest pain, heart attack or failure, or other heart problems.
- Signs of stroke such as slurred speech, limb weakness and facial drooping.
- Allergic reaction: signs may include hives or rashes on your skin, or swelling of your face, lips, mouth, tongue or throat.

Other side effects

Tell your doctor if you have any of the following problems:

Rare (may affect up to 1 in 1000 people)

- Dermatitis, joint pain or stiffness, dry eyes.
- Symptoms of Retroperitoneal fibrosis including: abdominal and lower back pain, decreased urination or total inability to urinate, and decreased circulation in the legs leading to pain, swelling and discolouration.

Not known (frequency cannot be estimated from the available data)

- Systemic lupus erythematosus (Lupus) – symptoms include joint pain or stiffness, extreme tiredness
- Muscle pain or weakness, worsening of myasthenia gravis.
- Cold or bluish hands and feet, low blood pressure, “pins and needles”, tingling in the hands or feet, pain in legs induced by exercise.
- Nausea (feeling sick), vomiting (being sick), diarrhoea, stomach pain, or cough.
- Dizziness or light headedness, vertigo or feeling faint, headaches, trouble with sleeping or nightmares.

- Low blood sugar.
- Visual disturbances, blurred or double vision, eye irritation, inflammation or redness, drooping of eyelid, pain and loss of vision after eye surgery.
- Depression, hallucinations, drowsiness, disorientation, confusion, memory loss or other mental problems.
- Dry mouth or disturbed taste.
- Sexual dysfunction, decreased libido.
- Hair loss.
- Worsening of psoriasis

Blood tests may show increased levels of antibodies.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. HOW TO STORE TIMOLOL MALEATE 10 MG TABLETS

Keep this medicine out of the sight and reach of children.

Do not use Timolol maleate 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.

This medicine requires no special storage conditions. 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 contains

Active substance: Timolol maleate (as maleate). Each tablet contains 10 mg of Timolol maleate maleate.

Other ingredients: Microcrystalline cellulose, pre-gelatinised starch and magnesium stearate.

What Timolol maleate looks like and contents of the pack

Timolol maleate 10 mg tablets are white, flat circular tablets. Each tablet is engraved with “ $\frac{V}{BET}$ ” on one side and a breakmark on the other.

The tablets are supplied in amber glass bottles, or packs containing aluminium blister strips, of 30 or 100 tablets.

Not all packs sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, UK

Manufacturer

Labiana Pharmaceuticals S.L.U., Casanova 27-31, 08757- Corbera de Llobregat (Barcelona), Spain.

For any information about this medicine, please contact Mylan.

This leaflet was last revised in September 2019.

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