

Tiopex[®] 1 mg/g, eye gel in single-dose container

(timolol maleate)

3044
05.09.23[8]

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- 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 of the side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Tiopex eye gel is and what it is used for
2. What you need to know before you use Tiopex eye gel
3. How to use Tiopex eye gel
4. Possible side effects
5. How to store Tiopex eye gel
6. Contents of the pack and other information

1. WHAT TIOPEX EYE GEL IS AND WHAT IT IS USED FOR

The full name of your medicine is Tiopex 1 mg/g, eye gel in single-dose container. It is called Tiopex eye gel in the rest of this leaflet.

This medicine is a beta-blocker administered to the eye. It is used for the treatment of certain types of eye disease involving high pressure in the eye (glaucoma and ocular hypertension).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE TIOPEX EYE GEL

Do not use Tiopex eye gel

- if you are allergic to timolol maleate, beta-blockers or any of the other ingredients of this medicine (listed in section 6),
- if you have now or have had in the past respiratory problems such as asthma, severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough),
- if you have a slow heart beat, heart failure or disorders of heart rhythm (irregular heart beats),
- in case of untreated pheochromocytoma (high blood pressure caused by high levels of a hormone due to a tumour near the kidney),
- in case of corneal dystrophies (alteration of the surface of the eye).

Take special care with Tiopex eye gel

If you use Tiopex eye gel, you will have to have regular checks of your eye and the pressure inside your eye.

Before you use this medicine, tell your doctor if you have now or have had in the past

- coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure, low blood pressure,
- disturbances of heart rate such as slow heart beat,
- breathing problems, asthma or chronic obstructive pulmonary disease (lung disease which may cause wheeziness, difficulty in breathing and/or long standing cough),
- poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome),
- diabetes as timolol maleate may mask signs and symptoms of low blood sugar,
- overactivity of the thyroid gland as timolol maleate may mask signs and symptoms,
- treated pheochromocytoma (high blood pressure due to a tumour near the kidney which you are taking medicine for),
- psoriasis,
- corneal disease (a disorder of the clear surface of the eye),
- metabolic disease (a disorder that changes the normal process of metabolism, converting food into energy inside the body).

Tell your doctor before you have an operation that you are using Tiopex eye gel as timolol maleate may change effects of some medicines used during anaesthesia.

Do not stop treatment suddenly without your doctor's advice.

Do not inject, do not swallow.

Children and adolescents

Do not give this medicine to children under the age of 18 years as it is unlikely to be safe.

Precautions for wearing contact lenses

- You should not wear contact lenses during treatment because less tears will be released; this is generally linked with beta-blockers.

Other medicines and Tiopex eye gel

If your doctor has prescribed another kind of eye drops for you, you should **use** these eye drops **15 minutes before** Tiopex eye gel.

Tiopex eye gel can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma.

Tell your doctor if you are using or intend to use medicines to lower blood pressure, heart medicine or medicines to treat diabetes, quinidine (used to treat heart conditions and some types of malaria) or antidepressants known as fluoxetine and paroxetine.

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

Pregnancy, breast-feeding and fertility

Do not use Tiopex eye gel if you are pregnant unless your doctor considers it necessary.

Do not use Tiopex eye gel if you are breast-feeding.

Timolol maleate may get into your milk.

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 and using machines

You may have blurred vision for a short time after using the product. Wait until your vision is normal before driving or using any machine. Tiopex eye gel may cause other side effects (dizziness, constant tiredness) likely to affect your ability to drive or to use machines. If you have any concerns, please ask your doctor.

Sport

The active ingredient in this medicine can produce a positive result during drug testing.

3. HOW TO USE TIOPEX EYE GEL

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

Dosage

The recommended dose is

- **Adults**
The usual dose is one drop in the affected eye(s), once a day, in the morning.
Each single-dose container contains enough gel to treat both eyes.
- **Children and adolescents**
There is no experience in children and adolescents.
Therefore these patients should not use this eye gel.
- **Elderly patients**
The dose is the same as for adults.

Frequency of administration

Apply one drop in the affected eye(s), once a day, in the morning.

Method of administration

This medicine is intended to be administered in the eye (ocular use).

For single use only.

- Wash your hands carefully before using your eye gel.

- **Shake the container vigorously, opening downwards, before applying a drop.**

- Do not allow the tip to come into contact with the eye or eyelids.
- Pull the lower lid of the affected eye gently downwards while looking upwards, and apply the drop into the eye.
- After using Tiopex eye gel press a finger into the corner of your eye, by the nose for 2 minutes. This helps to stop timolol maleate getting into the rest of the body.
- Discard the single-dose container after use. Do not keep it to use it again.

If you use more Tiopex eye gel than you should

Among other effects, you may feel as if you have dizziness, or you may have difficulty in breathing or feel that your pulse rate has slowed down.

Check with your doctor or pharmacist immediately.

If you forget to use Tiopex eye gel

Do not take a double dose to make up for a forgotten dose. Apply the forgotten dose as soon as possible.

However, if it is nearly time to take the next dose, simply miss out the forgotten dose.

If you stop using Tiopex eye gel

The pressure inside your eye may increase and damage your vision.

Do not stop treatment suddenly without your Doctor's advice.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines Tiopex eye gel can cause side effects although not everybody gets them.

You can usually carry on taking the drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist. Do not stop using Tiopex eye gel without speaking to your doctor.

Like other medicines applied into eyes, timolol maleate is absorbed into the blood. This may cause similar side effects as seen with 'intravenous' and/or 'oral' as applicable beta-blocking agents. Incidence of side effects after topical ophthalmic administration is lower than when medicines are, for example, taken by mouth or injected. Listed side effects include reactions seen within the class of beta-blockers when used for treating eye conditions:

- Disseminated lupus erythematosus, generalised allergic reactions including swelling beneath the skin (that can occur in areas such as the face and limbs, and can obstruct the airway which may cause difficulty swallowing or breathing), hives or itchy rash, localised and generalised rash, itchiness, severe sudden life-threatening allergic reaction.
- Low blood glucose levels.
- Difficulty sleeping (insomnia), depression, nightmares, memory loss, hallucination.
- Fainting, stroke, reduced blood supply to the brain, increases in signs and symptoms of myasthenia gravis (muscle disorder), dizziness, unusual sensations (like pins and needles), and headache.
- Signs and symptoms of eye irritation (e.g. burning, stinging, itching, tearing, redness), inflammation of the eyelid, inflammation in the cornea, blurred vision and detachment of the layer below the retina that contains blood vessels following filtration surgery which may cause visual disturbances, decreased corneal sensitivity, dry eyes, corneal erosion (damage to the front layer of the eyeball), drooping of the upper eyelid (making the eye stay half closed), double vision, changes in the way the eye sees where objects are (refraction, sometimes due to stopping treatment with miotic drops used for making the pupil of the eye smaller).
- Slow heart rate, chest pain, palpitations, oedema (fluid build up), changes in the rhythm or speed of the heartbeat, congestive heart failure (heart disease with shortness of breath and swelling of the feet and legs due to fluid build up), a type of heart rhythm disorder, heart attack, heart failure, leg cramps and/or leg pain when walking (claudication).
- Low blood pressure, Raynaud's phenomenon, cold hands and feet.
- Constriction of the airways in the lungs (predominantly in patients with pre-existing disease), difficulty breathing, cough.
- Taste disturbances, nausea, indigestion, diarrhoea, dry mouth, abdominal pain, vomiting.
- Hair loss, skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis, skin rash.
- Muscle pain not caused by exercise.
- Sexual dysfunction, decreased libido, impotence.
- Muscle weakness/tiredness.
- Positive results in anti-nuclear antibodies.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, nurse or Optometrist/Optician. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: 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 TIOPEX EYE GEL

- 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 carton, sachet and single-dose container after EXP. The expiry date refers to the last day of that month.
- Keep the single-dose containers in the sachet and the outer carton in order to protect from light.
- After opening of the single-dose container: use immediately and discard the single-dose container after use.
- After opening of the sachet, use the single-dose containers within 1 month.
- If the eye gel becomes discoloured or shows signs of any deterioration you should seek the advice of your pharmacist.
- Do not throw away any medicines via wastewater. 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 Tiopex eye gel contains

- The active substance is timolol. 1g of gel contains 1mg of timolol as timolol maleate.
- The other ingredients are sorbitol, polyvinyl alcohol, carbomer 974P, sodium acetate trihydrate, lysine monohydrate, water for injections.

What Tiopex eye gel looks like and the contents of the pack

Tiopex eye gel is an opalescent, colourless to slightly yellow eye gel, presented in single-dose containers packed in a sachet.

A pack size contains 30 (3 x 10) single-dose containers.

Manufacturer and product licence holder

Tiopex eye gel is manufactured by:

- Laboratoire Unither, Zi De La Guerie, 50211 Coutances Cedex, France.
- Laboratoire Unither, Espace Industriel Nord, 151 Rue Andre Durouchez, BP 28028, 80084 Amiens Cedex 2, France.
- Laboratoire Unither, 1 Rue de l'Arquerie, 50200 Coutances, France.

Procured from within the EU by product licence holder:

Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD.
Repackaged by Servipharm Ltd.

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Frequency of administration

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Method of administration

This medicine is intended to be administered in the eye (ocular use).
For single use only.

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- **Shake the container vigorously, opening downwards, before applying a drop.**
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- Low blood glucose levels.
- Difficulty sleeping (insomnia), depression, nightmares, memory loss, hallucination.
- Fainting, stroke, reduced blood supply to the brain, increases in signs and symptoms of myasthenia gravis (muscle disorder), dizziness, unusual sensations (like pins and needles), and headache.
- Signs and symptoms of eye irritation (e.g. burning, stinging, itching, tearing, redness), inflammation of the eyelid, inflammation in the cornea, blurred vision and detachment of the layer below the retina that contains blood vessels following filtration surgery which may cause visual disturbances, decreased corneal sensitivity, dry eyes, corneal erosion (damage to the front layer of the eyeball), drooping of the upper eyelid (making the eye stay half closed), double vision, changes in the way the eye sees where objects are (refraction, sometimes due to stopping treatment with miotic drops used for making the pupil of the eye smaller).
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5. HOW TO STORE TIMOLOL EYE GEL

- 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 carton, sachet and single-dose container after EXP. The expiry date refers to the last day of that month.
- Keep the single-dose containers in the sachet and the outer carton in order to protect from light.
- After opening of the single-dose container: use immediately and discard the single-dose container after use.
- After opening of the sachet, use the single-dose containers within 1 month.
- If the eye gel becomes discoloured or shows signs of any deterioration you should seek the advice of your pharmacist.
- Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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