Read all of this leaflet carefully before you start using this medicine.

1. What Timolol Eye Drops are and what they are used for

Timolol eye drop solution has been studied in infants and children aged 12 days to 5 years, and the 0.25% solution has been studied in children aged 12 days to 12 years. In infants and younger children Timolol should be used with extreme caution. If coughing, wheezing, abnormal breathing or abnormal pauses in breathing (apnoea) occur, the use of Timolol eye drop solution should generally be stopped immediately. Contact your doctor as soon as possible. If the benefits of treatment appear to be marginal, a detailed medical examination should precede the use of Timolol. Your doctor will carefully evaluate the risks and benefits when considering treatment with Timolol. If the benefits outweigh the risks, it is recommended to use the lowest active agent concentration available once daily. With regard to “the use in children” the 0.25% solution may be sufficient to control the raised intraocular pressure in children.

2. Before you use Timolol Eye Drops

Tell your doctor before you have an operation that you are using Timolol Eye Drops as timolol may change effects of some medicines used during anaesthesia. Do not use Timolol Eye Drops if you are breast-feeding. Timolol may get into your milk. Ask your doctor for advice before taking any medicine during breast-feeding. Do not use Timolol Eye Drops if you are breast-feeding. Timolol may get into your milk. Pregnancy and breast-feeding – guanethidine, a medicine used to treat high blood pressure – clonidine, a medicine used to treat high blood pressure – an SSRI (e.g. fluoxetine or paroxetine) often used to treat depression – a pressor amine (e.g. adrenaline) used to treat severe allergic reaction

3. HOW TO USE TIMOLOL EYE DROPS

Always use Timolol Eye Drops exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual starting dose is one drop of 0.25% w/v solution in the affected eye(s) twice a day (e.g. once in the morning and once in the evening). Some people need a stronger dose. Your doctor will change your treatment as necessary.

4. POSSIBLE SIDE EFFECTS

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE TIMOLOL EYE DROPS

This medicine has been prescribed for you. Do not pass it on others. It may harm them, even if their symptoms are the same as yours.

6. FURTHER INFORMATION

If you have any further questions, ask your doctor or pharmacist.

When using eyedrops:

- avoid touching the dropper tip against your eye or anything else.
- 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 – poor blood circulation disease (such as Raynaud’s disease or Raynaud’s syndrome) – diabetics may mask signs and symptoms of high blood sugar – overactivity of the thyroid gland as timolol may mask signs and symptoms

Take special care with Timolol Eye Drops

Always wash your hands before applying eye drops. Apply only one drop of Timolol Eye Drops in each affected eye in the following way:

1. Tilt your head back and look at the ceiling.
2. Gently pull the lower eyelid down until there is a small pocket.
3. Squeeze the upturned dropper bottle to release a drop into your eye.
4. Whilst keeping the affected eye closed, press your finger against the corner of the closed eye (the side where the eye meets the nose) and hold for as long as possible (e.g. 3 – 5 minutes). This helps to stop timolol getting into the rest of your body.
5. Replace and tighten the cap immediately after use.

Avoid touching the dropper tip against your eye or anything else.
If you use more Timolol Eye Drops than you should

There is no experience of an overdose of Timolol Eye Drops which is unlikely when used in the eye. If it has been swallowed, then you should contact your doctor.

If you did not have to use Timolol Eye Drops

If a dose has been forgotten treatment should continue with the next dose as planned. The dose should not exceed one drop twice daily (in the affected eye).

If you are using Timolol Eye Drops

Do not stop using this medicine without talking to your doctor first.

Duration of treatment for Paediatric population

For a transient period only

4. POSSIBLE SIDE EFFECTS

Like all medicines, Timolol Eye Drops 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 Timolol Eye Drops without speaking to your doctor.

Like other medicines applied into eyes, timolol is absorbed into the blood. This may cause similar side effects as seen with intraocular and/or oral beta-blocking agents. Incidence of side effects reported as local ocular—abnormal ocular reactions—lower than when medicines are for, 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.

If you develop 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, lives or tachy, localized and generalized rash, itchness, severe sudden life-threatening allergic reaction, stop taking your eye drops and seek medical attention immediately.

Low blood glucose levels.

Difficult sleeping (insomnia), depression, nightmares, memory loss.

Fainting, strike, reduced blood supply to the brain, increases in signs and symptoms of myasthenia gravis (muscle disorder), unusual sensations like tugging or 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 of 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 eyelid), drooping of the upper eyelid (making the eye stay half closed) double vision, visual disturbance, difference from the eye, pain in the eye.

Ringing sound in the ears.

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.

Low blood pressure, fainting, interference with the blood supply to the brain which may lead to a temporary lack of consciousness, emotional changes, blackouts, unsteadiness, dizziness, cold feeling, feeling faint, raising of the heart rate.

Taste disturbances, nausea, indigestion, diarrhoea, dry mouth, abdominal pain, vomiting.

Constriction of the airways in the lungs (predominantly in patients with pre-existing disease), difficulty breathing, shortness of breath, wheezing, cough.

Taste disturbances, nausea, indigestion, diarrhoea, dry mouth, abdominal pain, vomiting.

Sexual dysfunction, decreased sex drive, decreased libido. In men a condition which effects testosterone levels, in women a condition which effects sex hormones levels.

Hair loss, skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis, skin rash.

Double vision, sensitivity to light, discharge from the eye, pain in the eye, iritis (inflammation of the front layer of the eyeball), drooping of the upper eyelid (making the eye stay half closed) vision disturbances, decreased corneal sensitivity, dry eyes, corneal erosion (damage to the front layer of the eyelid), drooping of the upper eyelid (making the eye stay half closed) double vision, visual disturbance, itching of the eye, redness, pain in the eye.

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3. STORAGE OF TIMOLOL EYE DROPS

Keep out of reach and sight of children.

Do not use the bottle if the tamper-proof seal on the bottle is broken before first use.

Do not use Timolol Eye Drops after the expiry date which is stated on the label of the bottle and on the carton.

Do not use the same bottle 4 weeks after opening even if the bottle is not empty.

Do not use Timolol Eye Drops at a temperature above 25˚C.

Do not use the same bottle 4 weeks after opening even if the bottle is not empty.

Do not use Timolol Eye Drops for animals.

Do not use the same bottle 4 weeks after opening even if the bottle is not empty.

Do not use Timolol Eye Drops if the bottle has been kept at a temperature above 25˚C.

Do not use the bottle if the tamper-proof seal on the bottle is broken before first use.

Do not use Timolol Eye Drops if the bottle has been kept at a temperature above 25˚C.

Do not stop using this medicine without talking to your doctor first.

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Report any side effects to your doctor or pharmacist. It 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 EYE DROPS

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Do not stop using this medicine without talking to your doctor first.

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It is unlikely when used in the eye. If it has been swallowed, then you should contact your doctor.

If you did not have to use Timolol Eye Drops

If a dose has been forgotten treatment should continue with the next dose as planned. The dose should not exceed one drop twice daily (in the affected eye).

If you are using Timolol Eye Drops

Do not stop using this medicine without talking to your doctor first.

Duration of treatment for Paediatric population

For a transient period only

6. FURTHER INFORMATION

What Timolol Eye Drops contain

The active ingredient is timolol. Timolol Eye Drops are available in two strengths as follows:

Timolol 0.25% w/v Eye Drops Solution. 1 ml of solution contains 2.5 mg timolol (as timolol maleate).

Timolol 0.5% w/v Eye Drops Solution. 1 ml of solution contains 5 mg timolol (as timolol maleate).

Other ingredients are benzenzulonol chloride (preservative), disodium phosphate dodecahydrate, sodium dihydrogen phosphate dihydrate and water for injection.

What Timolol Eye Drops look like and contents of the pack

A transparent plastic (LDPE) bottle containing 5 ml of a clear and colourless solution.

Timolol 0.25% w/v or 0.5% w/v Eye Drops Solution

1 x 5 ml plastic bottle

3 x 5 ml plastic bottles

1 x 5 ml plastic bottle

23 Moortown Close

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NG31 9GG

Hard to see or read the leaflet? Call 01476 978568 for help.

This leaflet was last revised in October 2014

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Blumont Pharma

Marketing Authorisation Holder and Manufacturer

F-07104 Annonay Cedex

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