

Package leaflet: Information for the patient

Timoptol 0.25% w/v eye drops, solution

Timoptol 0.5% w/v eye drops, solution

timolol (as maleate)

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 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. See section 4.

What is in this leaflet:

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

1. What Timoptol is and what it is used for

Timoptol contains a substance called timolol which belongs to a group of medicines called beta-blockers. Timolol lowers the pressure in your eye(s). It is used to treat glaucoma, when the pressure in the eye is raised.

2. What you need to know before you use Timoptol

Do not use Timoptol if:

- you are allergic (hypersensitive) to timolol maleate, beta-blockers or any of the other ingredients of Timoptol (see section 6: Contents of the pack and other information)
- you have now or have had in the past respiratory problems, such as asthma, severe chronic obstructive bronchitis (severe lung condition which may cause wheeziness, difficulty in breathing and/or long-standing cough)
- you have heart problems
- slow heart beat, heart failure or disorders of heart rhythm (irregular heart beats)
- heart failure
 - “cardiogenic shock” – a serious heart condition caused by very low blood pressure, which may result in the following symptoms: dizziness and lightheadedness, fast pulse rate, white skin, sweating, restlessness, loss of consciousness.

If you are not sure whether you should use Timoptol talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor before taking Timoptol 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)

- diabetes as timolol may mask signs and symptoms of low blood sugar
- overactivity of the thyroid gland as timolol may mask signs and symptoms
- allergies to any medicines
- you wear soft contact lenses.

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

If your eye becomes irritated or any new eye problems come on, talk to your doctor straight away. Eye problems could include redness of the eye or swelling of the eyelids (see Section 4: Possible Side Effects).

If you suspect that Timoptol is causing an allergic reaction or hypersensitivity (for example, skin rash, or redness and itching of the eye), stop using Timoptol and contact your doctor immediately.

Tell your doctor if:

- you get an eye infection
- you injure your eye or have an operation on it
- your eye problems get worse or you get any new symptoms.

Children and adolescents

Timoptol eye drops, solution should generally be used with caution in young patients. In newborns, infants and younger children Timoptol should be used with extreme caution. If coughing, wheezing, abnormal breathing or abnormal pauses in breathing (apnoea) occur, the use of the medication should be stopped immediately. Contact your doctor as soon as possible. A portable apnoea monitor may also be helpful.

There is only very limited data available on the use of timolol in infants and children. For example, in one small clinical study, timolol, the active ingredient in Timoptol eye drops, was studied in infants and children aged 12 days to 5 years, who have raised pressure in the eye(s) or have been diagnosed with glaucoma. For more information, talk to your doctor.

Other medicines and Timoptol

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

It is important to tell your doctor before using Timoptol if you are taking one or more of the following medicines:

- a calcium antagonist, such as nifedipine, verapamil or diltiazem, often used to treat high blood pressure, angina, an abnormal heartbeat or Raynaud's syndrome
- digoxin, a medicine used to relieve heart failure or treat abnormal heartbeat
- medicines known as catecholamine-depleting agents, such as rauwolfia alkaloids or reserpine, used for high blood pressure
- medicines called pressor amines, such as adrenaline used to treat severe allergic reaction
- quinidine (used to treat heart conditions and some types of malaria)
- antidepressants known as fluoxetine and paroxetine
- clonidine, a medicine used to treat high blood pressure
- other beta-blockers taken by mouth or used as eye drops, because they belong to the same group of medicines as Timoptol and could have an additive effect.

Pregnancy and breast-feeding

Ask your doctor for advice before taking any medicine.

Use in pregnancy

Do not use Timoptol during pregnancy unless your doctor considers it necessary.

Use in breast-feeding

Do not use Timoptol if you are breastfeeding. Timolol may get into your milk. Ask your doctor for advice before taking any medicine during breast-feeding.

Driving and using machines

There are possible side effects associated with Timoptol, such as dizziness and changes in your eyesight, which may affect your ability to drive and/or operate machinery. Do not drive and/or operate machinery until you feel well and your vision is clear.

Timoptol contains benzalkonium chloride and phosphates

This medicine contains 0.10 mg/ml benzalkonium chloride as a preservative. Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

This medicine contains the following phosphates

- disodium phosphate dodecahydrate (29.21 mg/ml for Timoptol 0.25%, 30.42 mg/ml for Timoptol 0.5%)
- sodium dihydrogen phosphate dihydrate (8.15 mg/ml for Timoptol 0.25%, 6.10 mg/ml for Timoptol 0.5%)

If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

3. How to use Timoptol

Always use Timoptol eye drops, solution exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The doctor will decide how many drops you should take each day and how long you should use them.

The usual dose is one drop in the affected eye(s) twice each day:

- one in the morning
- one in the evening.

Do not change your usual dose without talking to your doctor.

Do not allow the tip of the bottle to touch the eye or areas around the eye. It may become contaminated with bacteria that can cause eye infection leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the bottle, keep the tip of the bottle away from contact with any surface.

Instructions for use

Do not use the bottle if the plastic safety strip around the neck is missing or broken. When opening the bottle for the first time, tear off the plastic safety strip.

Every time you use Timoptol:

1. Wash your hands.

2. Open the bottle. **Take special care that the tip of the dropper bottle does not touch your eye, the skin around your eye or your fingers.**

3. Tilt your head backwards and hold the bottle upside down over the eye.



4. Pull the lower eyelid downwards and look up. Hold and gently squeeze the bottle on the flattened sides of the bottle and let one drop fall into the space between the lower eyelid and the eye.



5. Press a finger into the corner of your eye, by the nose, or close your eyelids for 2 minutes. This helps to stop the medicine from getting into the rest of the body.



6. Repeat steps 3 to 5 with the other eye if instructed to do so by your doctor.

7. Put the cap back on and close the bottle tightly.

Ophthalmic medications, if handled improperly, can become contaminated by common bacteria known to cause infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated ophthalmic medications. If you think your medication may be contaminated, or if you develop an eye infection, contact your doctor immediately concerning continued use of this bottle.

Use in children and adolescents

A detailed medical examination should precede the use of Timoptol. Your doctor will carefully evaluate the risks and benefits when considering treatment with Timoptol. 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 0.1% active agent concentration may be sufficient to control pressure within the eye. If the pressure is not sufficiently controlled with this dosage, a twice daily application at 12-hourly intervals may be necessary. Patients, especially newborn, should be closely observed for one to two hours after the first dose and careful monitoring for adverse events should be carried out until surgery is performed.

Method of administration:

One drop only of Timoptol should be instilled per dosing time. After instillation keep the eyes closed for as long as possible (e.g. 3 – 5 minutes) and apply pressure to the corner of the eye closest to the nose to prevent Timoptol eye drops spreading throughout the body.

Duration of treatment:

For a transient treatment in the paediatric population.

If you use more Timoptol than you should

If you put too many drops in your eye or swallow any of the drops, you may:

- have a headache
- feel dizzy or light-headed
- have difficulty breathing
- feel that your heart rate has slowed down.

If this happens, contact your doctor immediately.

If you forget to use Timoptol

It is important to take Timoptol as prescribed by your doctor.

- If you miss a dose, use the drops as soon as possible.
- If it is almost time for the next dose, skip the missed dose and take the next dose at the usual time.
- Do not take a double dose to make up for the forgotten dose.

If you stop using Timoptol

If you want to stop using this medicine talk to your doctor first. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If they do occur, you may need medical attention.

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 Timoptol without speaking to your doctor.

In some patients side effects may include:

Allergic reactions

- allergic skin rash and hives
- severe allergic reaction which causes difficulty in breathing or dizziness.

Eyes and ears

- burning and stinging
- dry eyes
- irritation and redness of the eye or eyelid
- sensitivity to light
- discharge from the eye
- visual changes such as double vision
- decreased sensation of your eye surface
- pain in your eye
- drooping of the upper eyelid (making the eye stay partially closed)
- ringing in your ears.

Heart and circulation

- chest pain
- heart attack
- fainting
- stroke
- palpitations
- changes in the rhythm or speed of the heartbeat
- a slowing of your heart rate
- low blood pressure
- reduced blood supply to the brain
- oedema (too much fluid, mainly water, accumulating in the body)
- limping because there is a reduced blood supply to your legs

- swelling or coldness of your hands, feet and extremities, caused by constriction of your blood vessels.

Chest

- wheezing
- shortness of breath
- difficulty breathing
- cough.

Stomach and gut

- nausea
- diarrhoea
- indigestion
- vomiting
- dry mouth.

Sexual

- decreased sex drive (libido)
- in men a condition which effects your penis called Peyronie's disease. The signs may be abnormal curve, pain or hardening of the tissue of your penis.

Skin and hair

- hair loss
- a skin disease called psoriasis, where areas of skin such as knees and elbows are covered in scales with white silvery coloured appearance
- worsening of psoriasis.

Nervous system

- dizziness
- depression
- difficulty sleeping
- nightmares
- memory loss
- increase in signs and symptoms of myasthenia gravis
- unusual sensations like pins and needles
- tingling sensation
- hallucination.

General

- headache
- tiredness
- muscle weakness
- a condition called lupus (systemic lupus erythematosus).

If you suffer from severe damage to the clear layer at the front of the eye (the cornea) phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

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

- generalised allergic reactions including swelling beneath the skin, localised and generalised rash, itchiness, severe life-threatening allergic reaction
- Low blood glucose levels
- cerebrovascular accident

- signs and symptoms of eye irritation (e.g. burning, stinging, itching, tearing, redness), inflammation of the eyelid, inflammation in the cornea (front layer of the eyeball), 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, corneal erosion (damage to the cornea)
- congestive heart failure (heart disease with shortness of breath and swelling of the feet and legs due to fluid build up), atrioventricular block, (a type of heart rhythm disorder), heart attack, heart failure.
- Raynaud's phenomenon
- Constriction of the airways in the lungs causing difficulty breathing (predominantly in patients with pre-existing disease)
- Taste disturbances, abdominal pain.
- muscle pain not caused by exercise
- sexual dysfunction.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below).

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

HPRA Pharmacovigilance, website: www.hpra.ie

5. How to store Timoptol

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

- Do not store above 25°C.
- Keep the bottle in the outer carton in order to protect from light.
- You can use Timoptol for 28 days after first opening the bottle.

Do not use Timoptol after the expiry date which is stated on the carton and the bottle after EXP. The expiry date refers to the last day of that month. Make sure the bottle is properly closed.

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 to protect the environment.

6. Contents of the pack and other information

What Timoptol contains

The active substance is timolol maleate.

Timoptol is available in two strengths:

- 0.25% w/v solution of timolol (as maleate)
- 0.5% w/v solution of timolol (as maleate).

The other ingredients are:

- benzalkonium chloride as preservative
- disodium phosphate dodecahydrate E339
- sodium dihydrogen phosphate dihydrate E339
- sodium hydroxide
- water for injections.

What Timoptol looks like and contents of the pack

Timoptol is a clear colourless to light yellow sterile eye drops solution and is available in bottles containing 5 ml of sterile eye drops solution.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Santen Oy
Niittyhaankatu 20
33720 Tampere
Finland

Manufacturer

Santen Oy
Kelloportinkatu 1
33100 Tampere
Finland

This leaflet was last revised in March 2020.

This leaflet gives the most important patient information about Timoptol. If you have any questions after you have read it, ask your doctor or pharmacist who will give you further information.

Further information about glaucoma is available from:

International Glaucoma Association (IGA)
15A Highpoint Business Village
Henwood, Ashford
Kent, TN24 8DH
Tel: +44 (0) 1233 648170
E-mail: info@iga.org.uk
Registered Charity number 274681.

(The IGA is an independent charity organisation which helps glaucoma patients and their relatives and is not associated with Santen Oy.)

Alternatively, if you or someone you know has problems with their vision, and you require further advice or information, please contact:

National Council for the Blind of Ireland, Whitworth Road, Drumcondra, Dublin 9. Tel: 01 8307033
or Fax: 01 8307787 charity registration number: CHY 4626

(The National Council for the Blind of Ireland is an independent Irish charity and is not associated with Santen Oy.)

Leaflet for Mirabel

Package leaflet: Information for the patient

Timoptol 0.25% w/v eye drops, solution

Timoptol 0.5% w/v eye drops, solution

timolol (as maleate)

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2. What Timoptol is and what it is used for

Timoptol contains a substance called timolol which belongs to a group of medicines called beta-blockers. Timolol lowers the pressure in your eye(s). It is used to treat glaucoma, when the pressure in the eye is raised.

3. What you need to know before you use Timoptol

Do not use Timoptol if:

- you are allergic (hypersensitive) to timolol maleate, beta-blockers or any of the other ingredients of Timoptol (see section 6: Contents of the pack and other information)
- you have now or have had in the past respiratory problems, such as asthma, severe chronic obstructive bronchitis (severe lung condition which may cause wheeziness, difficulty in breathing and/or long-standing cough)
- you have heart problems

- slow heart beat, heart failure or disorders of heart rhythm (irregular heart beats)
- heart failure
 - “cardiogenic shock” – a serious heart condition caused by very low blood pressure, which may result in the following symptoms: dizziness and lightheadedness, fast pulse rate, white skin, sweating, restlessness, loss of consciousness.

If you are not sure whether you should use Timoptol talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor before taking Timoptol 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)
- diabetes as timolol may mask signs and symptoms of low blood sugar
- overactivity of the thyroid gland as timolol may mask signs and symptoms
- allergies to any medicines
- you wear soft contact lenses.

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

If your eye becomes irritated or any new eye problems come on, talk to your doctor straight away. Eye problems could include redness of the eye or swelling of the eyelids (see Section 4: Possible Side Effects).

If you suspect that Timoptol is causing an allergic reaction or hypersensitivity (for example, skin rash, or redness and itching of the eye), stop using Timoptol and contact your doctor immediately.

Tell your doctor if:

- you get an eye infection
- you injure your eye or have an operation on it
- your eye problems get worse or you get any new symptoms.

Children and adolescents

Timoptol eye drops, solution should generally be used with caution in young patients. In newborns, infants and younger children Timoptol should be used with extreme caution. If coughing, wheezing, abnormal breathing or abnormal pauses in breathing (apnoea) occur, the use of the medication should be stopped immediately. Contact your doctor as soon as possible. A portable apnoea monitor may also be helpful.

There is only very limited data available on the use of timolol in infants and children. For example, in one small clinical study, timolol, the active ingredient in Timoptol eye drops, was studied in infants and children aged 12 days to 5 years, who have raised pressure in the eye(s) or have been diagnosed with glaucoma. For more information, talk to your doctor.

Other medicines and Timoptol

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

It is important to tell your doctor before using Timoptol if you are taking one or more of the following medicines:

- a calcium antagonist, such as nifedipine, verapamil or diltiazem, often used to treat high blood pressure, angina, an abnormal heartbeat or Raynaud's syndrome
- digoxin, a medicine used to relieve heart failure or treat abnormal heartbeat
- medicines known as catecholamine-depleting agents, such as rauwolfia alkaloids or reserpine, used for high blood pressure
- medicines called pressor amines, such as adrenaline used to treat severe allergic reaction
- quinidine (used to treat heart conditions and some types of malaria)
- antidepressants known as fluoxetine and paroxetine
- clonidine, a medicine used to treat high blood pressure
- other beta-blockers taken by mouth or used as eye drops, because they belong to the same group of medicines as Timoptol and could have an additive effect.

Pregnancy and breast-feeding

Ask your doctor for advice before taking any medicine.

Use in pregnancy

Do not use Timoptol during pregnancy unless your doctor considers it necessary.

Use in breast-feeding

Do not use Timoptol if you are breastfeeding. Timolol may get into your milk. Ask your doctor for advice before taking any medicine during breast-feeding.

Driving and using machines

There are possible side effects associated with Timoptol, such as dizziness and changes in your eyesight, which may affect your ability to drive and/or operate machinery. Do not drive and/or operate machinery until you feel well and your vision is clear.

Timoptol contains benzalkonium chloride and phosphates

This medicine contains 0.10 mg/ml benzalkonium chloride as a preservative. Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

This medicine contains the following phosphates

- disodium phosphate dodecahydrate (29.21 mg/ml for Timoptol 0.25%, 30.42 mg/ml for Timoptol 0.5%)
- sodium dihydrogen phosphate dihydrate (8.15 mg/ml for Timoptol 0.25%, 6.10 mg/ml for Timoptol 0.5%)

If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

3. How to use Timoptol

Always use Timoptol eye drops, solution exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The doctor will decide how many drops you should take each day and how long you should use them.

The usual dose is one drop in the affected eye(s) twice each day:

- one in the morning
- one in the evening.

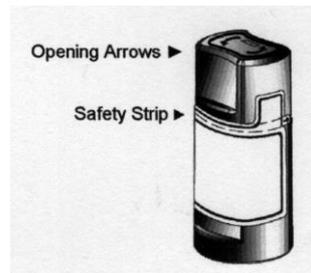
Do not change your usual dose without talking to your doctor.

Do not allow the tip of the bottle to touch the eye or areas around the eye. It may become contaminated with bacteria that can cause eye infection leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the bottle, keep the tip of the bottle away from contact with any surface.

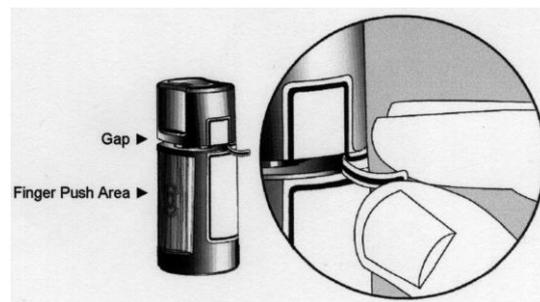
Instructions for use

It is recommended that you wash your hands before putting in your eye drops.

1. Before using the medication for the first time, be sure the Safety Strip on the front of the bottle is unbroken. A gap between the bottle and the cap is normal for an unopened bottle



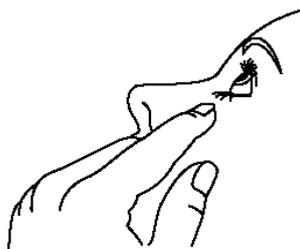
2. Tear off the safety strip to break the seal.



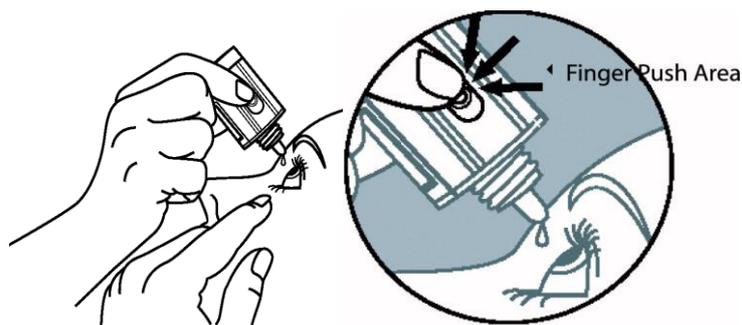
3. To open the bottle, unscrew the cap by turning as indicated by the arrows on top of the cap. Do not pull the cap directly up and away from the bottle. Pulling the cap directly up will prevent your dispenser from operating properly.



4. Tilt your head back and pull your lower eyelid down slightly to form a pocket between your eyelid and your eye.



5. Invert the bottle, and press lightly with your thumb or first finger over the 'Finger-Push Area' as shown until a single drop is dispensed into your eye, as directed by your doctor.



DO NOT TOUCH YOUR EYE OR EYELID WITH THE DROPPER TIP.

6. After using Timoptol, press a finger into the corner of your eye, by the nose for 2 minutes. This helps to stop timolol getting into the rest of your body.

Ophthalmic medications, if handled improperly, can become contaminated by common bacteria known to cause infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated ophthalmic medications. If you think your medication may be contaminated, or if you develop an eye infection, contact your doctor immediately concerning continued use of this bottle.
7. If drop dispensing is difficult after opening for the first time, replace the cap on the bottle and tighten (do not overtighten) and then remove by turning the cap in the opposite direction as indicated by the arrows on top of the cap.
8. Repeat steps 4 & 5 with the other eye if instructed to do so by your doctor.
9. Replace the cap by turning until it is firmly touching the bottle. The arrow on the left side of the cap must be aligned with the arrow on the left side of the bottle label for proper closure. Do not overtighten or you may damage the bottle and cap.
10. The dispenser tip is designed to provide a single drop; therefore do NOT enlarge the hole of the dispenser tip.
11. After you have used all doses there will be some Timoptol left in the bottle. You should not be concerned since an extra amount of Timoptol has been added and you will get the full amount of Timoptol that your doctor has prescribed. Do not attempt to remove the excess medicine from the bottle.

Use in children and adolescents

A detailed medical examination should precede the use of Timoptol. Your doctor will carefully evaluate the risks and benefits when considering treatment with Timoptol. 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 0.1% active agent concentration may be sufficient to control pressure within the eye. If the pressure is not sufficiently controlled with this dosage, a twice daily application

at 12-hourly intervals may be necessary. Patients, especially newborn, should be closely observed for one to two hours after the first dose and careful monitoring for adverse events should be carried out until surgery is performed.

Method of administration:

One drop only of Timoptol should be instilled per dosing time. After instillation keep the eyes closed for as long as possible (e.g. 3 – 5 minutes) and apply pressure to the corner of the eye closest to the nose to prevent Timoptol eye drops spreading throughout the body.

Duration of treatment:

For a transient treatment in the paediatric population.

If you use more Timoptol than you should

If you put too many drops in your eye or swallow any of the drops, you may:

- have a headache
- feel dizzy or light-headed
- have difficulty breathing
- feel that your heart rate has slowed down.

If this happens, contact your doctor immediately.

If you forget to use Timoptol

It is important to take Timoptol as prescribed by your doctor.

- If you miss a dose, use the drops as soon as possible.
- If it is almost time for the next dose, skip the missed dose and take the next dose at the usual time.
- Do not take a double dose to make up for the forgotten dose.

If you stop using Timoptol

If you want to stop using this medicine talk to your doctor first. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If they do occur, you may need medical attention.

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 Timoptol without speaking to your doctor.

In some patients side effects may include:

Allergic reactions

- allergic skin rash and hives
- severe allergic reaction which causes difficulty in breathing or dizziness.

Eyes and ears

- burning and stinging
- dry eyes
- irritation and redness of the eye or eyelid
- sensitivity to light
- discharge from the eye
- visual changes such as double vision
- decreased sensation of your eye surface
- pain in your eye
- drooping of the upper eyelid (making the eye stay partially closed)
- ringing in your ears.

Heart and circulation

- chest pain

- heart attack
- fainting
- stroke
- palpitations
- changes in the rhythm or speed of the heartbeat
- a slowing of your heart rate
- low blood pressure
- reduced blood supply to the brain
- oedema (too much fluid, mainly water, accumulating in the body)
- limping because there is a reduced blood supply to your legs
- swelling or coldness of your hands, feet and extremities, caused by constriction of your blood vessels.

Chest

- wheezing
- shortness of breath
- difficulty breathing
- cough.

Stomach and gut

- nausea
- diarrhoea
- indigestion
- vomiting
- dry mouth.

Sexual

- decreased sex drive (libido)
- in men a condition which effects your penis called Peyronie's disease. The signs may be abnormal curve, pain or hardening of the tissue of your penis.

Skin and hair

- hair loss
- a skin disease called psoriasis, where areas of skin such as knees and elbows are covered in scales with white silvery coloured appearance
- worsening of psoriasis.

Nervous system

- dizziness
- depression
- difficulty sleeping
- nightmares
- memory loss
- increase in signs and symptoms of myasthenia gravis
- unusual sensations like pins and needles
- tingling sensation
- hallucination.

General

- headache
- tiredness
- muscle weakness
- a condition called lupus (systemic lupus erythematosus).

If you suffer from severe damage to the clear layer at the front of the eye (the cornea) phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

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

- generalised allergic reactions including swelling beneath the skin, localised and generalised rash, itchiness, severe life-threatening allergic reaction
- Low blood glucose levels
- cerebrovascular accident
- signs and symptoms of eye irritation (e.g. burning, stinging, itching, tearing, redness), inflammation of the eyelid, inflammation in the cornea (front layer of the eyeball), 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, corneal erosion (damage to the cornea)
- congestive heart failure (heart disease with shortness of breath and swelling of the feet and legs due to fluid build up), atrioventricular block, (a type of heart rhythm disorder), heart attack, heart failure.
- Raynaud's phenomenon
- Constriction of the airways in the lungs causing difficulty breathing (predominantly in patients with pre-existing disease)
- Taste disturbances, abdominal pain.
- muscle pain not caused by exercise
- sexual dysfunction.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below).

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

HPRA Pharmacovigilance, website: www.hpra.ie.

5. How to store Timoptol

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

- Do not store above 25°C.
- Keep the bottle in the outer carton in order to protect from light.
- You can use Timoptol for 28 days after first opening the bottle.

Do not use Timoptol after the expiry date which is stated on the carton and the bottle after EXP. The expiry date refers to the last day of that month. Make sure the bottle is properly closed.

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 to protect the environment.

6. Contents of the pack and other information

What Timoptol contains

The active substance is timolol maleate.

Timoptol is available in two strengths:

- 0.25% w/v solution of timolol (as maleate)
- 0.5% w/v solution of timolol (as maleate).

The other ingredients are:

- benzalkonium chloride as preservative
- disodium phosphate dodecahydrate E339

- sodium dihydrogen phosphate dihydrate E339
- sodium hydroxide
- water for injections.

What Timoptol looks like and contents of the pack

Timoptol is a clear colourless to light yellow sterile eye drops solution and is available in bottles containing 5 ml of sterile eye drops solution.

Marketing Authorisation Holder and Manufacturer**Marketing Authorisation Holder**

Santen Oy
Niittyhaankatu 20
33720 Tampere
Finland

Manufacturer

Laboratories Merck Sharp & Dohme – Chibret (Mirabel)
Route de Marsat
RIOM 63963 Clermont –Ferrand
Cedex 9
France

This leaflet was last revised in November 2019.

This leaflet gives the most important patient information about Timoptol. If you have any questions after you have read it, ask your doctor or pharmacist who will give you further information.

Further information about glaucoma is available from:

International Glaucoma Association (IGA)
15A Highpoint Business Village
Henwood, Ashford
Kent, TN24 8DH
Tel: +44 (0) 1233 648170
E-mail: info@iga.org.uk
Registered Charity number 274681.

(The IGA is an independent charity organisation which helps glaucoma patients and their relatives and is not associated with Santen Oy.)

Alternatively, if you or someone you know has problems with their vision, and you require further advice or information, please contact:

National Council for the Blind of Ireland, Whitworth Road, Drumcondra, Dublin 9. Tel: 01 8307033
or Fax: 01 8307787 charity registration number: CHY 4626

(The National Council for the Blind of Ireland is an independent Irish charity and is not associated with Santen Oy.)

