Read all of this leaflet carefully before you start using 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 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.

This product is also available in other strengths.

Your medicine is called as Timoptol® 0.5% w/v Eye Drops Solution, but it will be referred as Timoptol throughout this leaflet.

In this leaflet:

1. What Timoptol is and what it is used for
2. Before you use Timoptol
3. How to use Timoptol
4. Possible side effects
5. How to store Timoptol
6. Further information

1. WHAT TIMOPTOL IS AND WHAT IT IS USED FOR

Timoptol contains a substance called timolol maleate 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. 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 for Further Information)
- you have now or have had in the past respiratory problems such as asthma, severe chronic obstructive bronchitis (severe lung disease which may result in the following symptoms: breathlessness, difficulty in breathing and/or long-standing cough)
- you have heart problems
- slow heart beat
- dizers 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.

Take special care with Timoptol

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
- 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
- you wear soft contact lenses. Your eye drops contain a preservative which can be deposited on soft contact lenses. It is important that your lenses are removed before using your eye drops and not put back into your eyes for 15 minutes.

Tell your doctor before you have an operation that you are using Timoptol as timolol maleate 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.

Use in children and adolescents

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

For more information, talk to your doctor.

Timoptol 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.

Using other medicines

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 for treatment of heart conditions. 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 methyldopa, allopurinol 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 if you are pregnant unless your doctor considers it necessary.

Use in breast-feeding

Do not use Timoptol if you are breast-feeding. Timolol maleate 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, tiredness and changes in your eyesight, such as blurred vision, drooping of the upper eyelid (making the eye stay half closed), double vision 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.

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:

- once in the morning
- once in the evening.

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

Do not allow the tip of the container 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 container, keep the tip of the container 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 unknown. 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.

Instructions for use

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Driving and using machines

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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.
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 maleate 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.

If you stop using Timoptol as prescribed by your doctor, your eye may become inflamed and red again. This may cause discomfort and may require you to use Timoptol again. You may therefore need to use Timoptol for life.

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

7. FURTHER INFORMATION

What Timoptol contains
The active substance is timolol maleate. Each ml contains timolol maleate equivalent to 5mg of timolol. The other ingredients are: benzalkonium chloride as preservative, disodium phosphate dodecahydrate, sodium dihydrogen phosphate dihydrate, sodium hydroxide, water for injections.

What Timoptol looks like and contents of the pack
The OCUUMETER Plus ophthalmic dispenser consists of a translucent high-density polyethylene container with a sealed dropper tip. The OCUUMETER Plus ophthalmic dispenser contains 5 ml of solution. The solution is clear, colourless to light yellow, sterile eye drops solution.

Manufactured by: Laboratories Merck Sharp & Dohme, Chibret (Mirabel), Route de Marsat, Riom 63963 Clermont, Ferrand Cedex 9, France.

Procured from within the EU & repackaged by Product Licence Co., Inc., Whitehouse Station, New Jersey, U.S.A.

Timoptol® 0.5% w/v Eye Drops Solution, PL 39352/0054

Leaflet date: 20/07/2016

Timoptol® is a registered trademark of Merck & Corp., a subsidiary of Merck & Co., Inc., Whitehouse Station, New Jersey, U.S.A.
Read all of this leaflet carefully before you start using 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

This product is also available in other strengths. Your medicine is called as Timolol 0.5% w/v Eye Drops Solution, but it will be referred as Timolol throughout this leaflet.

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

Timolol contains a substance called Timolol maleate 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. BEFORE YOU USE TIMOLOL

Do not use Timolol if:

- you are allergic (hypersensitive) to Timolol maleate, beta-blockers or any of the other ingredients of Timolol (see section 6 for Further Information).
- 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).
- you have heart problems
- slow heart beat
- 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 Timolol talk to your doctor or pharmacist.

### Take special care with Timolol

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
- 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
- you wear soft contact lenses.
- your eye drops contain a preservative which can be deposited on soft contact lenses. It is important that your lenses are removed before using your eye drops and not put back into your eyes for 15 minutes.

Tell your doctor before you have an operation that you are using Timolol as timolol maleate 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 Timolol is causing an allergic reaction or hypersensitivity (for example, skin rash, or redness and itching of the eye), stop using Timolol 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.

### Use in children and adolescents

There is only very limited data available on the use of timolol maleate in infants and children.

- For example, in one small clinical study, timolol maleate, the active ingredient in Timolol eye drops, has been studied in infants and children.
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- For example, in one small clinical study, timolol maleate, the active ingredient in Timolol eye drops, has been studied in infants and children.

There are possible side effects associated with Timolol, such as dizziness, tiredness and changes in your eyesight, such as blurred vision, drooping of the upper eyelid (making the eye stay half closed), double vision 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.

### 3. HOW TO USE TIMOLOL

Always use Timolol 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 taking to your doctor.
  - Do not allow the tip of the container to touch the eye or 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 container, keep the tip of the container away from contact with any surface.

### Instructions for use:

Do not use Timolol in the future.

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.

### Further information

Further information on medicines called beta-blockers, such as adrenaline used to treat severe allergy 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 Timolol 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 Timolol if you are pregnant unless your doctor considers it necessary.

Use in breast-feeding

Do not use Timolol if you are breast-feeding. Timolol maleate 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 Timolol, such as dizziness, tiredness and changes in your eyesight, such as blurred vision, drooping of the upper eyelid (making the eye stay half closed), double vision 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.

- It is recommended that you wash your hands before putting in your eye drops.
- Do not use Timolol on your eyes for 15 minutes.
- Pulling the cap directly up will prevent your dispenser from operating properly.
- Do not use Timolol on your eyes for 15 minutes.
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.

6. After using Timolol, 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 your body.

7. If drop dispensing is difficult after opening for the first time, replace the cap on the bottle and lighten (do not overlight) 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. If you forget to use Timolol, do not use a double dose to make up for the one you missed. You should not be concerned if you develop an eye infection, contact your doctor immediately.

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 Timolol left in the bottle. You should not be concerned since an extra amount of Timolol has been added and you will get the full amount of Timolol that your doctor has prescribed. Do not attempt to remove the excess medicine from the bottle.

Use in children and adolescents
Before you or your child starts to take Timolol, your doctor or your child’s doctor will have carried out a detailed medical examination and decided whether or not this medicine is suitable. You or your child, especially a newborn, should be closely monitored for one to two hours after the first dose and carefully monitored for any signs of side effects until surgery is carried out.

Method of administration:
One drop only of Timolol should be instilled into the affected eye(s) each time.

1. After the "Instructions for Use" above when administering the eye drops.

2. 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 the eye drops spreading throughout the body.

Duration of treatment:
Your doctor or your child’s doctor will decide for how long the eye drops will be needed.

If you use more Timolol 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
• chest pain
• feel that your heart rate has slowed down.

If this happens, contact your doctor immediately.

If you forget to use Timolol
It is important to take Timolol 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 Timolol
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.

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. List 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, hives or itchy rash, localised and generalized rash, itchiness, severe sudden life-threatening allergic reaction, stop taking your eyes drops and seek medical attention immediately.

Low blood glucose levels.

Dizziness or feeling faint, unusual tiredness or weakness, unusual anxiety or excitement, feeling restless, sleeplessness, depression, muscle weakness, tremor or shaking, sweating, headache.

Dizziness or feeling faint, unusual tiredness or weakness, unusual anxiety or excitement, feeling restless, sleeplessness, depression, muscle weakness, tremor or shaking, sweating, headache.

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5. HOW TO STORE TIMOLOL
Keep your eye drops out of the sight and reach of children.

• Do not store your eye drops above 25°C.

• Store the bottle in the outer carton in order to protect from light.

• You can open the bottle for 38 days after first opening the bottle.

Do not use Timolol 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 container is properly closed.

Medicines should 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. FURTHER INFORMATION
What Timolol contains
The active substance is Timolol maleate.

Each ml contains timolol maleate equivalent to 5mg of timolol.

The other ingredients are:

• benzalkonium chloride as preservative
• disodium phosphate dodecahydrate
• sodium hydrogen carbonate dihydrate
• sodium hydroxide
• water for injections

What Timolol looks like and contents of the pack
The OCUMLER Plus ophthalmic dispenser consists of a translucent high-density polyethylene container with a sealed dropper tip. The OCUMLER Plus ophthalmic dispenser contains 5 ml of solution. The solution is clear, colorless to light yellow, sterile eye drops solution.

Manufactured by: Laboratories Merek Sharp & Dohme, Chibret (Mirabel), Route de Marsart, B-36936 Clermont, Ferrand Cedex 9, France.

Procured from within the EU & repackaged by Product Licence holder: Kosel Pharma UK Ltd., 956 Buckingham Avenue, Slough Trading Estate, Slough, SL1 4NL, UK.

Timolol 0.5% w/v Eye Drops Solution, PL 39352/0054
Leaflet date: 20/07/2016

4. POSSIBLE SIDE EFFECTS
Like all medicines Timolol 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 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 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. 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, hives or itchy rash, localised and generalized rash, itchiness, severe sudden life-threatening allergic reaction, stop taking your eyes drops and seek medical attention immediately.

Low blood glucose levels.

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