IOTIM EYE DROPS

Timolol Maleate (0.5 w/v)

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What Iotim Eye Drops is used for

Iotim Eye Drops is used to treat elevated pressure in eye in people with ocular hypertension or open angle glaucoma.

How Iotim Eye Drops works

Iotim Eye Drops when applied topically in the eye has the action of reducing elevated pressure in the eye.

Before you use Iotim Eye Drops

- When you must not use it

If you are allergic (hypersensitive) to Timolol or beta-blockers or to any other ingredient of this medicine.

If you have now or have had in the past breathing problems such as asthma, severe chronic obstructive lung disease which may cause difficulty in breathing and/or long-standing cough.

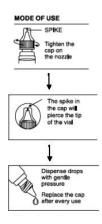
If you have a slow heartbeat, heart failure or disorders of heart rhythm (irregular heartbeats)

- <u>Before you start use it</u>
 It is important to tell your doctor before using Iotim Eye
 Drops
- Diabetes as timolol may mask signs and symptoms of low blood sugar
- Over activity of the thyroid gland as timolol may mask signs and symptoms.
- <u>Taking other medicines</u> Please inform your doctor if you are taking following medicines:
- Epinephrine use to treat very serious allergic reactions
- Reserpine use to treat high blood pressure
- Digitalis use for heart problems

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use Iotim Eye Drops

- <u>How much to use</u> Instil one drop in the affected eye(s) twice daily or as directed by the physician.



- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Iotim Eye Drops for as long as your doctor recommends.

- If you forget to use it

Apply the drops as soon as you remember. However, if it is almost time for your next dose, do not double your dose and carry on with the normal schedule dose.

<u>If you use too much</u> (overdose)

If you accidentally use too much contact your doctor immediately. The signs of over dosage include irregular heartbeat, headache, shortness of breath, slow heartbeat, breathing difficulties and heart stop beating, high blood pressure, dizziness, ringing in the ears, faintness and increased pulse rate.

While you are using it

- <u>Things you must do</u>

Take your medicine exactly as your doctor has told you. Tell all the doctors and pharmacists treating you that you are taking Iotim Eye Drops.

Tell your doctor immediately if you become pregnant while using this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Iotim Eye Drops to anyone else, even if they have the same symptoms or condition as you.

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Things to be careful of

Pregnancy and breast feeding.

Do not use Iotim Eye Drops if you are pregnant unless your doctor considers it necessary.

Do not use Iotim 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. Safety and effectiveness in children have not been established.

Driving and using machines

However, do not drive or operate machines if you experience any visual disturbance after using the product. Wait until this clears before driving or using machines.

Side effects

Local irritation is the only commonly observed adverse reaction. Shortage of breathing is reported in elderly with lung problem. Iotim Eye Drop is generally well tolerated following topical application to the eye.

- Eye irritation including burning and stinging sensation
- Inflammation of conjunctiva, eyelid or cornea
- visual disturbance including power changes
- decreased corneal sensitivity
- · double vision
- dropping of upper eyelid due to paralysis
- headache
- · depression
- dizziness
- an abnormal sensation such as tingling, tickling,

- pricking, numbness or burning of skin
- abnormal physical weakness or lack of energy
- diarrhoea
- nausea
- More serious side effects
- Heart block or worsening of the conditions
- irregular heartbeats
- congestive heart failure
- temporary loss of consciousness caused by fall in blood pressure
- stroke
- · stuffy nose
- cough with breathing difficulty (mainly in people with pre-existing asthma)
- respiratory failure (inability to breathe)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03- 78835549, or visiting the website npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)".

Storage and Disposal of Iotim Eye Drops.

- <u>Storage</u>

Store below 30°C & Protect from light.

Keep medicine away from the reach of children.

Use the solution within one month after opening the vial.

- <u>Disposal</u>

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.

Product Description

- What it looks like

5 ml sterile clear colourless solution in a plastic vial in a carton

- <u>Ingredients</u>

- Active ingredient Timolol Maleate
- Inactive ingredients
 Sodium Phosphate,
 Sodium Acid
 Phosphate, Disodium
 Edetate, Sodium
 Chloride,
 Benzalkonium
 Chloride, Sodium
 Hydroxide and Water
 for Injection.
- <u>MAL number</u>: MAL19990571AZ

Manufacturer:

FDC Limited. B-8, MIDC Industrial Area, Waluj, Aurangabad – 431 136, Maharastra, India

Product Registration Holder

Idaman Pharma Sdn Bhd. No 15 & 17, Jalan Wangsa Delima 1A, Seksyen 5, Pusat Bandar Wangsa Maju, 53300 Kuala Lumpur, Malaysia.

Date of revision:

29/08/2018

Serial Number:

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