

LATACOM (LATANOPROST 0.005% + TIMOLOL 0.5%) EYE DROPS

Latanoprost 50mcg/ml and Timolol 5mg/ml

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What LATACOM is used for

Reduction of intraocular pressure, in patients with open angle glaucoma and ocular hypertension who are insufficiently responsive to topical beta-blockers.

LATACOM is used to reduce the pressure in your eye if you have conditions known as open angle glaucoma or ocular hypertension. Both these conditions are linked to an increase in the pressure within your eye, eventually affecting your eyesight. Your doctor will usually prescribe you LATACOM when other medicines have not worked adequately.

How LATACOM works

LATACOM contains two medicines: latanoprost and timolol. Latanoprost belongs to a group of medicines known as prostaglandin analogues. Timolol belongs to a group of medicines known as beta-blockers. Latanoprost works by increasing the natural outflow of fluid from the eye into the bloodstream.

Timolol works by slowing the formation of fluid in the eye.

Before you use LATACOM

LATACOM can be used in adult men and women (including the elderly), but is not recommended for use if you are less than 18 years of age.

- When you must not take it

Do not use LATACOM:

- If you are allergic (hypersensitive) to either of the medicines in LATACOM (latanoprost or timolol), beta-blockers, or any of the other ingredients of LATACOM.
- 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 serious heart problems or heart rhythm disorders.

Pregnancy and lactation:

Do not use LATACOM if you are pregnant unless your doctor considers it necessary. Tell your doctor immediately if you are pregnant, think you are pregnant or are planning to become pregnant.

Do not use LATACOM if you are breast-feeding. Ask your doctor for advice before taking any medicine during breast-feeding.

- Before you start to use it:

Talk to your doctor or pharmacist before using LATACOM if you have now or have had in the past:

- Coronary heart disease [symptoms can include chest pain, including angina (particularly a type known as Prinzmetal angina), or tightness, breathlessness or choking], heart failure, low blood pressure
- Other disturbances of heart rate or heart rhythm 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, or episodes of low blood sugar, as timolol may mask signs and symptoms of low blood sugar
- Overactivity of the thyroid gland as timolol may mask signs and symptoms
- You are about to have any kind of eye surgery (including cataract surgery) or have had any kind of eye surgery in the past
- Have any eye problems (eye pain, irritation or inflammation or blurred vision)
- You know that you suffer from dry eyes
- You wear contact lenses. You can still use LATACOM but follow the instructions for contact lens wearers. (See Section How to use LATACOM)
- You know that you suffer from severe allergic reactions that would usually require hospital treatment.

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- You have suffered or are currently suffering from a viral infection of the eye caused by the herpes simplex virus (HSV).

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

- Taking other medicines

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.

LATACOM 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, to treat heart conditions or to treat diabetes.

In particular, speak to your doctor or pharmacist if you know that you are taking any of the following types of medicines:

- Prostaglandins, prostaglandin analogues or prostaglandin derivatives
- Adrenaline (Epinephrine)
- Drugs used to treat high blood pressure such as oral calcium channel blockers, beta-adrenergic blocking agents, guanethidine, antiarrhythmics, digitalis glycosides or parasympathomimetics
- Quinidine (used to treat heart conditions and some types of malaria)
- Antidepressants, such as

fluoxetine and paroxetine

- Timolol
- Clonidine

How to use LATACOM

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained the instruction on the label, ask your doctor or pharmacist for help.

The usual dosage for adults (including the elderly) is one drop once a day in the affected eye (s).

- When to use it

Use as directed by your doctor and pharmacist.

Use in children:

LATACOM is not recommended for children or adolescents under 18 years of age.

- How long to use it

Continue taking LATACOM for as long as your doctor recommends.

Your doctor may want you to have extra checks on your heart and circulation if you use LATACOM.

- If you forget to use it

If one dose is missed, treatment should continue with the next dose as planned. The dose should not exceed one drop in the affected eye (s) daily.

- If you use too much (Overdose)

If you put too many drops in your eye you may experience some minor irritation in your eye and your eyes may water and turn red. This should pass but if you are

worried contact your doctor or pharmacist for advice.

If you swallow LATACOM accidentally you should contact your doctor or pharmacist for advice.

If you swallow a lot of LATACOM, you may feel sick, have stomach pains, feel tired, flushed and dizzy and start to sweat.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking LATACOM.

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

Contact lens wearers:

If you wear contact lens, you should remove them before using LATACOM. After using LATACOM you should wait 15 minutes before putting your contact lenses back in.

- 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 or pharmacist.

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

- Things you must be careful of

Driving and using machines

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When you use LATACOM your vision may become blurred for a short time. If this happens to you, do not drive or use any tools or machines until your vision becomes clear again.

LATACOM contains a preservative called benzalkonium chloride. This preservative may cause eye irritation or disruption on the surface of the eye. It can be absorbed by contact lenses and is known to discolour soft contact lenses. Therefore, avoid contact with soft contact lenses. See the instructions for contact lens wearers in section while you are using it.

Side Effects

Like all medicines, LATACOM can cause side effects, although not everybody gets them. Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

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 LATACOM without speaking to your doctor.

The most important side-effect is the possibility of a gradual, permanent change in your eye colour. It is also possible that LATACOM might cause serious changes in the way your heart works.

If you notice changes in your heart rate or heart function you should speak to a doctor and tell them you have been using LATACOM.

The following are known side

effect of using LATACOM.

Very Common (may effect more than 1 in 10 people) :

A gradual change in your eye colour by increasing the amount of brown pigment in the coloured part of the eye known as the iris. If you have mized-colour eyes (blue-brown, grey-brown, yellow-brown or green-brown). Any changes in your eye colour may take years to develop. The colour change may be permanent and may be more noticeable if you use LATACOM in only one eye. There appears to be no problems associated with the change in eye colour. The eye colour change does not continue after LATACOM treatment is stopped.

Common (may effect up to 1 in 10 people):

Eye irritation (a feeling of burning, grittiness, itching, stinging or the sensation of a foreign body in the eye) and eye pain.

Other side effects

Although not seen with LATACOM, the following additional side effects have been seen with the medicines in LATACOM (Latanoprost and Timolol) and therefore might occur when you use LATACOM.

-Infections and Infestations: Developing a viral infection of the eye caused by the herpes simplex virus (HSV).

-Nervous System Disorder: Dizziness, tingling or numbness in the skin, changes in blood flow to the brain, worsening of symptoms of myasthenia gravis (if you already

suffer from this condition), sudden fainting or feeling you may faint (syncope), headache.

-Eye Disorders: Changes to the eyelashes and fine hairs around the eye (increased number, length, thickness, and darkening), changes to the direction of eyelash growth, swelling around the eye, swelling of the coloured part of the eye (iritis/uveitis), swelling at the back of the eye (macular oedema), inflammation/ irritation of the surface of the eye (keratitis), dry eyes, visual changes/disturbances, double vision, drooping of the upper eyelid, injury to the lining of the back of the eye (a condition known as retinal detachment, but only seen when used following some kind of eye surgery), fluid filled cyst with the coloured part of the eye (iris cyst) appearance of calcium on the central cornea.

-Heart (cardiac) Disorders: Worsening of angina, awareness of heart rhythm (palpitations), changes in heart rhythm, slowing of the heart, heart failure (cardiac arrest, heart block or congestive heart failure).

-Breathing (Respiratory) Disorders: Asthma, worsening of asthma, shortness of breath, sudden difficulty to breathe (bronchospasm), cough.

-Skin Disorders: Darkening of the skin around the eyes, hair loss/baldness (alopecia), itchy rash or worsening of itchy skin conditions.

-Muscle and Skeletal Disorders:

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Joint pain, muscle pain.

-General Disorders: Chest pain, fatigue, swelling (oedema).

-Immune System Disorders: Symptoms of allergic reaction (swelling and redness of the skin and rash)

-Psychiatric Disorders: Depression, memory loss, inability to sleep, nightmares.

-Ear Disorders: Whistling/ringing in ears (tinnitus).

-Blood Flow (Vascular) Disorders: Low blood pressure, discolouration/coldness of the fingers and toes (Raynaud's phenomenon) and coldness of the hands and feet.

-Digestive System(Gastrointestinal) Disorders: Feeling sick (nausea), diarrhea, dyspepsia, dry mouth, vomiting.

-Reproductive System and Breast Disorders: Sexual dysfunction, decreased libido.

If you get any side effects talk to your doctor. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Monitoring by visiting the website npra.moh.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of

LATACOM

- Storage

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

Store unopened bottle(s) at 2 to 8°C (refrigerated) and once opened at room temperature 25°C for 4 weeks. Protect from light.

- Disposal

Do not use 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.

Product Description

- What it looks like

LATACOM is a clear colourless solution in an eye drop bottle with insert and cap.

Each bottle contains 2.5 ml eye drops solution corresponding to approximately 104 drops of solution.

- Ingredients

Active ingredient:

1 ml of LATACOM contains 50 micrograms of Latanoprost and 6.8 mg Timolol Maleate equivalent to 5 mg of Timolol.

Inactive ingredients:

Benzalkonium Chloride Solution 50% (preservative), Sodium Chloride, Sodium Dihydrogen Phosphate, Disodium Hydrogen Phosphate and water for injection.

-MAL number:

MAL20116018AZ

Manufacturer:

Duopharma (M)Sendirian Berhad
Lot 2599, Jalan Seruling 59,
Kawasan 3, Taman Klang Jaya,
41200 Klang, Selangor Darul
Ehsan, Malaysia

Product Registration Holder:

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Lot 2599, Jalan Seruling 59,
Kawasan 3, Taman Klang Jaya,
41200 Klang, Selangor Darul
Ehsan, Malaysia

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