Package leaflet: Information for the user

Vizilatan® Duo

50 micrograms/mL + 5 mg/mL eye drops, solution

latanoprost/timolol

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

1. What Vizilatan Duo is and what it is used for

Vizilatan Duo 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.

Vizilatan Duo 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 Vizilatan Duo when other medicines have not worked adequately.

Vizilatan Duo can be used in adult men and women (including the elderly), but is not recommended for use in children and adolescents under 18 years of age.

2. What you need to know before you use Vizilatan Duo

Do not use Vizilatan Duo
- if you are allergic to latanoprost or timolol, beta-blockers, or any of the other ingredients of this medicine (listed in section 6).
- if you have now or have had in 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.

Warnings and precautions

Talk to your doctor or pharmacist before using Vizilatan Duo 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 (hyperthyroidism), 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
- you suffer from eye problems (such as eye pain, eye irritation, eye inflammation or blurred vision)
- you know that you suffer from dry eyes
- you wear contact lenses. You can still use Vizilatan Duo, but follow the instructions for contact lens wearers in section 3.
- you know that you suffer from angina (particularly a type known as Prinzmetal angina)
- you know that you suffer from severe allergic reactions that would usually require hospital treatment
- 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 Vizilatan Duo as timolol may change effects of some medicines used during anaesthesia.

Children and adolescents

Vizilatan Duo is not recommended for use if you are less than 18 years of age.

Other medicines and Vizilatan Duo

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including eye drops and medicines obtained without a prescription.

Vizilatan Duo 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.

In particular, talk to your doctor or pharmacist if you know that you are taking any of the following types of medicine:
- Prostaglandins, prostaglandin analogues or prostaglandin derivates (used in the treatment of glaucoma, gastric ulcers, pulmonary hypertension, dilation of blood vessels and erectile dysfunction) such as alprostadil, iloprost, bimatoprost and misoprostol
- Beta-blockers (used to treat high blood pressure, angina, some abnormal heart rhythms, heart attack, anxiety, migraine, glaucoma, and overactive thyroid symptoms) such as atenolol, bisoprolol and metoprolol.
- Epinephrine (used to treat life-threatening allergic reactions caused by insect bites or stings, foods, medications, latex, and other causes)
- Medicines used to treat high blood pressure such as oral calcium channel blockers (for example diltiazem and verapamil), guanethidine, antiarrhythmics (such as digoxin, flecainide and sotalol), digitalis glycosides or parasympathomimetics such as acetylcholine.
- Quinidine (used to treat heart conditions and some types of malaria)
- Antidepressants known as fluoxetine and paroxetine

Vizilatan Duo with food and drink

Normal meals, food or drink have no effect on when or how you should use Vizilatan Duo.

Pregnancy, breast-feeding and fertility

Pregnancy

Do not use Vizilatan Duo if you are pregnant unless your doctor considers it necessary. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Breast-feeding

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

Fertility

Latanoprost and timolol have been found to have no effect on male or female fertility in animal studies.

Driving and using machines

When you use Vizilatan Duo 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.

Vizilatan Duo contains macrogolglycerol hydroxystearate 40

This medicine contains macrogolglycerol hydroxystearate 40, which may cause skin reactions.

Vizilatan Duo contains phosphate buffer

This medicine contains 0.18 mg phosphates in each drop which is equivalent to 6.43 mg/ml.

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.

Vizilatan Duo eye drops, solution is a sterile solution that does not contain a preservative.

3. How to use Vizilatan Duo

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

Do not use Vizilatan Duo more than once a day, because the effectiveness of the treatment can be reduced if you administer it more often.

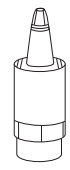
Use Vizilatan Duo as instructed by your doctor until your doctor tells you to stop.

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

Contact lens wearers

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

Instructions for use

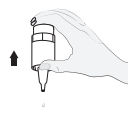


1a

- Take the bottle (**picture 1a**) out of the carton box and write the date of opening on the carton box in the space provided.
- Get the medicine bottle and a mirror.
- Wash your hands.
- Remove the cap (**picture 1b**).



1b



2

- Hold the bottle upside down with the thumb on the shoulder of the bottle and the other fingers on the bottom of the bottle.
- Before the first use, pump the bottle repeatedly fifteen (15) times (**picture 2**). A possible whitish appearance of the drops should not cause concern.



3

- Tilt your head back. Pull down your eyelid with a clean finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in here (**picture 3**).
- Bring the bottle tip close to the eye. Use the mirror if it helps.
- **Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper.** It could infect the drops.



4

- Gently press down on the bottom side of the bottle to release one drop of medicine at a time (**picture 4**). If a drop misses your eye, try again.



5

- After using the medicine, press a finger into the corner of your eye, by the nose, for 2 minutes (**picture 5**). This helps to stop the medicine getting into the rest of the body.
- If you use drops in both eyes, repeat these same steps for your other eye.
- Close the bottle cap firmly immediately after use.
- Only use one bottle of medicine at a time. Do not open the cap until you need to use the bottle.
- **Stop using the bottle 4 weeks after you first opened it,** to prevent infections, and use a new bottle.

If you use Vizilatan® Duo with other eye drops
Wait at least 5 minutes between using Vizilatan Duo and using the other eye drops.

If you use more Vizilatan Duo than you should
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 for advice.

If you swallow Vizilatan Duo
If you swallow Vizilatan Duo accidentally you should contact your doctor for advice. If you swallow a lot of Vizilatan Duo you may feel sick, have stomach pains, feel tired, flushed and dizzy and start to sweat. In normal use, eye drops drain via tear ducts into the nose, and then into the throat where they may be swallowed. This should not be cause for concern.

If you forget to use Vizilatan Duo
Carry on with the usual dose at the usual time. Do not use a double dose to make up for a forgotten dose. If you are unsure about anything, talk to your doctor or pharmacist.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You can usually carry on using the drops, unless the effects are serious. If you are worried, talk to a doctor or pharmacist. Do not stop using Vizilatan Duo without talking to your doctor.

Listed below are the known side effects of using eye drops containing the active substances latanoprost and timolol. The most important side effect is the possibility of a gradual, permanent change in your eye colour. It is also possible that eye drops containing the active substances latanoprost and timolol 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 Vizilatan Duo.

The following are known side effects of using eye drops containing the active substances latanoprost and timolol:

Very common (may affect 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 mixed-colour eyes (blue-brown, greybrown, yellow-brown or green-brown) you are more likely to see this change than if you have eyes of one colour (blue, grey, green or brown eyes). 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 Vizilatan Duo 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 Vizilatan Duo treatment is stopped.

Common (may affect 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

Uncommon (may affect up to 1 in 100 people):
- Headache
- Redness of the eye, eye infection (conjunctivitis), blurred vision, watery eyes, inflammation of the eyelids, irritation or disruption of the surface of the eye
- Skin rashes or itching (pruritus)

Other side effects
Like other medicines used in the eyes, latanoprost and timolol are absorbed into the blood. The incidence of side effects after using eye drops is lower than when medicines are, for example, taken by mouth or injected.

Although not seen with eye drops containing both the active substances latanoprost and timolol, the following side effects have been seen with either of the active substances in Vizilatan Duo and, therefore, might occur when you use Vizilatan Duo. The listed side effects include reactions seen within the class of beta-blockers (e.g. timolol) when used for treating eye conditions:
- Developing a viral infection of the eye caused by the herpes simplex virus (HSV)
- Generalized 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, localized and generalized rash, itchiness, severe sudden life-threatening allergic reaction
- Low blood glucose (sugar) levels
- Dizziness
- Difficulty sleeping (insomnia), depression, nightmares, memory loss, hallucination
- Fainting, stroke, reduced blood supply to the brain, increases in signs and symptoms of myasthenia gravis (muscle disorder), unusual sensations like pins and needles and headache
- Swelling at the back of the eye (macular oedema), fluid filled cyst within the coloured part of the eye (iris cyst), light sensitivity (photophobia), sunken eye appearance (deepening of the eye sulcus)
- 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 below 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 eyeball), drooping of the upper eyelid (making the eye stay half closed), double vision
- Darkening of the skin around the eyes, 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), scarring of the surface of the eye
- Whistling/ringing in the ears (tinnitus)
- Angina, worsening of angina in patients who already have heart disease
- Slow heart rate, chest pain, palpitations (awareness of heart rhythm), 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, poor blood circulation which makes the fingers and toes numb and pale, cold hands and feet
- Shortness of breath, constriction of the airways in the lungs (predominantly in patients with pre-existing disease), difficulty breathing, cough, asthma, worsening of asthma
- Taste disturbances, nausea (uncommon), indigestion, diarrhoea, dry mouth, abdominal pain, vomiting (uncommon)
- Hair loss, skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis, skin rash
- Joint pain, muscle pain not caused by exercise, muscle weakness, tiredness
- Sexual dysfunction, decreased libido

In very rare cases, some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment.

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 via the Yellow Card Scheme.

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Vizilatan Duo

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

Do not use this medicine after the expiry date which is stated on the carton and the bottle label after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Stop using the bottle 4 weeks after you first opened it, to prevent infections. Write down the date you opened the bottle in the space on the carton.

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 protect the environment.

6. Contents of the pack and other information

What Vizilatan Duo contains
- The active substances are latanoprost and timolol. Each mL of solution contains 50 micrograms of latanoprost and 5 mg of timolol (as 6.8 mg of timolol maleate).
- The other ingredients are macrogolglycerol hydroxystearate 40, sodium chloride, disodium edetate, sodium dihydrogen phosphate dihydrate, disodium phosphate, hydrochloric acid or/and sodium hydroxide (for pH adjustment), water for injections.

What Vizilatan Duo looks like and contents of the pack
Vizilatan Duo is presented as a 2.5 mL clear, colourless, aqueous solution, free from visible particles in a carton containing a 5 mL white multidose container (HDPE) with pump (PP, HDPE, LDPE) and orange pressure cylinder and cap (HDPE).

Pack sizes:
Cartons containing 1 or 3 bottles of 2.5 mL solution

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Bausch and Lomb UK Ltd.
106 London Road
Kingston-Upon-Thames
Surrey, KT2 6TN, UK

Manufacturer
Lomapharm GmbH
Langes Feld 5
31860 Emmerthal
Germany

PHARMATHEN S.
Dervenakion 6
Pallini 15351
Attiki
Greece

Bausch Health Poland sp. z o.o.
ul. Przemysłowa 2, 35-959 Rzeszów
Poland

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