Patient Information Leaflet

SCHEDULING STATUS

S4

OPTENSIN, 0,3 mg/mL, eye drops (solution)

Bimatoprost

Read all of this leaflet carefully before you start taking / using / are given OPTENSIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- OPTENSIN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What OPTENSIN is and what it is used for

OPTENSIN contains bimatoprost 0,3 mg per 1 ml eye drop solution. Bimatoprost is an antiglaucoma medicine that belongs to a group of medicines called prostamides.

OPTENSIN is used to reduce high pressure in the eye. It can be used on its own or with other eye drops called beta-blockers which also reduce pressure in the eye.

Your eye contains a clear, watery liquid. This liquid is constantly drained out of the eye and new liquid is made to replace this. If the liquid cannot drain out of the eye quickly enough, the

pressure inside the eye builds up and could eventually damage your sight, an illness called glaucoma. OPTENSIN works by reducing the production of this liquid and also by increasing the amount of liquid that is drained. This reduces the pressure inside the eye. If the high pressure in the eye is not reduced, it could lead to a disease called glaucoma and eventually damage your sight.

2. What you need to know before you use OPTENSIN

Do not use OPTENSIN:

- if you are allergic to bimatoprost or any of the other ingredients of OPTENSIN.

Warnings and precautions

Take special care with OPTENSIN:

- If you have asthma, chronic obstructive pulmonary disease or any breathing problems.
- If you have liver or kidney problems.
- If you have dry eyes, if you have (or have had) any problems with your cornea (front transparent part of the eye) or if you have extensive eye surface disease.
- If you wear contact lenses (see “OPTENSIN contains benzalkonium chloride”).
- If you have or have had low blood pressure or slow heart rate.
- If you have had a viral infection or inflammation of the eye.

If any of the above apply to you, tell your doctor before you take OPTENSIN. Your doctor will decide, if you should be treated with this medicine and if you should be kept under closer observation. You may be required to go for regular eye tests.

OPTENSIN may cause your eyelashes to darken and grow. The skin around the eyelid may darken too and the colour of your iris may also go darker over time. Hair may grow where OPTENSIN comes into contact with the skin (see “HOW TO USE OPTENSIN”). These changes may be permanent and may be more noticeable if you are only treating only one eye.

Children and adolescents

Do not give this medicine to children below the age of 18 years as it is unlikely to be safe.

Other medicines and OPTENSIN:

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

OPTENSIN 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 have used any other medicines including those medicines (or eye drops) obtained without a prescription.

If you use OPTENSIN with another eye medicine, wait at least 5 minutes between using OPTENSIN and the other medicine.

OPTENSIN with food and drink

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

Pregnancy and breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Do not use OPTENSIN if you are pregnant or breastfeeding.

Driving and using machines

When you use OPTENSIN 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.

It is not always possible to predict to what extent OPTENSIN may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which OPTENSIN affects you.

OPTENSIN contains benzalkonium chloride

This medicine contains a preservative called benzalkonium chloride.

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.

3. How to use OPTENSIN

Do not share medicines prescribed for you with any other person.

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

The usual dose is one (1) drop daily, instilled either in the morning or in the evening in each eye that needs treatment. Use OPTENSIN at the same time each day.

If you use OPTENSIN with other eye drops

If you use OPTENSIN with another eye medicine, wait at least 5 minutes between using OPTENSIN and the other medicine.

Instructions for use

1. Wash your hands before use.
2. Remove the screwcap.
3. Tilt your head back and look at the ceiling.
4. Gently pull down the lower eyelid until there is a small pocket.
5. Turn the bottle upside down and squeeze it to release one drop into each eye that needs treatment. To avoid contamination, do not let the tip of the bottle touch your eye, the area around your eyes or anything else.

6. Let go of the lower lid and close your eye.
7. Whilst keeping the eye closed, press your finger against the corner of the closed eye (the site where the eye meets the nose) and hold for 2 minutes. This helps to stop OPTENSIN getting into the rest of the body.
8. Put the cap back on and close the bottle straight after you have used it.

To help prevent infections and avoid eye injury, do not let the tip of the bottle touch your eye or anything else.

Your doctor will tell you how long your treatment with OPTENSIN will last.

If you have the impression that the effect of OPTENSIN is too strong or too weak, tell your doctor or pharmacist.

If you use more OPTENSIN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you use more OPTENSIN than you should, it is unlikely to cause you any serious harm.

Contact your doctor as soon as possible if you or your child swallows OPTENSIN accidentally.

If you forget to use OPTENSIN

If you have missed a dose, continue with the next dose as planned. Do not use more than one (1) drop in the affected eye or eyes per day.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking OPTENSIN

Do not stop treatment early because OPTENSIN prevents the development of serious conditions.

4. Possible side effects

OPTENSIN can have side effects.

Not all side effects reported for OPTENSIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking OPTENSIN, please

consult your health care provider for advice.

If any of the following happens, stop taking OPTENSIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to OPTENSIN. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects affecting the eye:

- longer and / or darker eyelashes, slight redness, itchiness, an allergic reaction in the eye, tired eyes, sensitivity to light, darker skin colour around the eye, pain, a feeling that something is in your eye, sticky eyes, darker iris colour, difficulty in seeing clearly, irritation, burning and inflamed, red and itchy eyelids.
- tears, dryness, worsening of vision, blurred vision, swelling of the see-through layer which covers the surface of the eye and small breaks in the surface of the eye, with or without inflammation.
- prostaglandin analogue periorbitopathy (PAP) - eyelid
  and orbital changes and eyes may appear sunken.

Frequent side effects affecting other parts of the body:

- Headaches.
- an increase in blood-test results that show how your liver is working.
- increased blood pressure.

Less frequent side effects affecting the eye:

- cystoid macular oedema (swelling of the retina within the eye leading to worsening vision), inflammation within the eye, retinal bleeding, swollen eyelids, eyelid twitching, eyelid shrinking and moving away from surface of the eye and skin redness around the eye.

Less frequent side effects affecting other parts of the body:

- infections, mostly colds and upper respiratory tract infections.
- nausea.
- dizziness.
- weakness.
- hair growth.
- swelling of the extremities (hands, feet, ankles and legs).
- periocular skin pigmentation.

Side effects where the frequency is not known affecting the eye:

- Ocular discomfort

Side effects where the frequency is not known affecting other parts of the body:

- asthma.
- worsening of asthma.
- worsening of the lung disease called chronic obstructive pulmonary disease (COPD).
- shortness of breath.
- symptoms of allergic skin reaction (swelling, redness and rash of the skin).

Side effects reported with eye drops containing phosphates:

OPTENSIN contains dibasic sodium phosphate heptahydrate. 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist.

You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of OPTENSIN.

5. How to store OPTENSIN

Store all medicines out of reach of children.

Store at or below 25 ºC in the original carton.

Once the bottle is opened the contents must be used within 28 days and may be stored at room temperature at or below 25 ºC.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What OPTENSIN contains

The active substance is bimatoprost 0,3 mg.

The other ingredients are benzalkonium chloride, citric acid monohydrate, dibasic sodium phosphate heptahydrate, sodium chloride and purified water.

What OPTENSIN looks like and contents of the pack

The solution is a clear, colourless liquid free from particles, packed in 5mL white LDPE bottles with white, tamper-proof HDPE screw cap and white LDPE dropper insert packed into a unit carton containing 1 bottle.

Each bottle contains 2,5 mL or 3 mL eye drop solution.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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