Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Vyzulta 0.024%
Eye drops, solution

Active ingredient

latanoprostene bunod 0.024% w/v (0.24 mg/ml)

Inactive ingredients and allergens in this medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

For the reduction of interocular pressure in patients with open-angle glaucoma or ocular hypertension.

Therapeutic group: F2 prostaglandin analog.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (listed in section 6).

Special warnings about using this medicine

Talk to your doctor before or when taking Vyzulta if:

- A new eye disturbance developed (e.g., trauma, inflammation or infection)
- You experience a sudden decrease in visual acuity
- You are supposed to undergo/are undergoing eye surgery
- You develop any eye reactions, particularly conjunctivitis and eyelid reactions. See also 'Additional warnings' and section 4 'Side effects'.
- You do not have a natural lens or had an artificial lens implanted with a torn posterior lens capsule, or you have known risk factors for macular edema.
- You have a history of intraocular inflammation (iritis/uveitis).

Additional warnings

Pigmentation (dark spots)

During use of the medicine increased brown pigmentation of the iris may appear, which may be permanent. Additionally, you may also notice eyelid skin darkening, which is usually

reversible after discontinuation of the treatment with Vyzulta. Iris color change may not be noticeable for several months to years.

If you develop noticeably increased iris pigmentation, you should be examined regularly.

The long-term effects of increased pigmentation are not known.

Eyelash changes

While using the medicine, there may be changes to your eyelashes and vellus hair in the treated eye, including increased length, thickness and the number of lashes or hairs. These changes may result in a disparity between eyes in length or thickness of the eyelashes or vellus hairs, color of the eyelashes or vellus hairs, their number and/or direction of eyelash growth. Eyelash changes are usually reversible upon discontinuation of treatment.

Intraocular inflammation

Your doctor will take precautions when Vyzulta is prescribed for patients with a history of intraocular inflammation (iritis/uveitis) and should generally not be used in patients with active intraocular inflammation as it may exacerbate the inflammation.

Macular edema

Macular edema, including cystoid macular edema, has been reported during treatment with prostaglandin analogs. Your doctor will take precautions when Vyzulta is prescribed for patients who do not have a natural lens, patients who have had an artificial lens implanted with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

Bacterial keratitis

There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products. These containers had been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface.

Use in the elderly

No differences in safety and efficacy of the medicine have been observed between elderly patients and adult patients.

Use in children and adolescents

Use in children aged 16 years and younger is not recommended because of safety concerns related to increased pigmentation following long-term chronic use.

Interactions with other medicines

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. See also section 3 ‘Use with other ophthalmic drugs’.

Using this medicine and food

The effect of food on taking the medicine is not known.

Using this medicine and alcohol consumption

The effect of alcohol on taking the medicine is not known.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you are pregnant or are planning to become pregnant, tell your doctor before using this medicine.

There is no data for the use of the medicine during pregnancy or while breastfeeding.

Driving and using machines

When using Vyzulta, it is possible that you may temporarily suffer from blurred vision. If this happens to you, do not drive or operate dangerous machinery until vision becomes clear again.

Important information about some of this medicine's ingredients

Vyzulta contains 0.2 mg benzalkonium chloride in every 1 ml of solution, equal to 0.02% w/v.

Benzalkonium chloride is a preservative that may be absorbed by soft contact lenses and may discolor them.

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 experience a strange eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

The recommended dose is usually: one drop in the treated eye/eyes once daily in the evening.

Do not exceed the recommended dose.

If you have accidentally taken a higher dosage

If the drops are instilled too frequently, the effectiveness of the treatment decreases.

If you forget to take the medicine, consult your doctor.

Do not swallow! This medicine is intended for use in the eyes only.

Avoid allowing the tip of the dispensing container to come into contact with the eye, surrounding structures, fingers or any other surface in order to avoid contamination of the solution by common bacteria known to cause eye infections.

Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

Use with contact lenses

If you wear contact lenses, remove them prior to administration of the solution. Lenses may be reinserted into the eyes 15 minutes after administration of Vyzulta.

Use with other ophthalmic drugs

If Vyzulta is intended for use in combination with other topical ophthalmic medicines, the medicines should be administered with at least five (5) minutes between them.

Adhere to the treatment as recommended by your doctor.

If a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using Vyzulta may cause side effects in some users. Do not be alarmed by reading the list of side effects, you may not suffer from any of them.

Contact your doctor immediately if:

- A new eye disturbance developed (e.g., trauma, inflammation or infection)
- You experience a sudden decrease in visual acuity
- You develop any eye reactions, particularly conjunctivitis and eyelid reactions

Common side effects - affect 1-10 in 100 users

Conjunctival hyperemia, eye irritation, eye pain and instillation site pain.

Additional side effects

- Ocular hyperemia, conjunctival irritation, conjunctival edema, vision blurred, punctate keratitis and foreign body sensation.
- Pigmentation, eyelash changes, intraocular inflammation, macular edema, bacterial keratitis – see section 2 under 'Special warnings regarding the use of this medicine'.

If you experience any side effect, if any side effect gets worse or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

- **Storage conditions:**
  Before opening, store the unopened bottle refrigerated between 2°C and 8°C. Protect from light. Do not freeze.
  After first opening of the bottle, the medicine can be used for up to 8 weeks when stored at 2°C to 25°C (refrigerated or not), and no later than the expiry date on the medicine.

6. Additional information

In addition to the active ingredient, this medicine also contains:
glycerin, sodium citrate dihydrate, polysorbate 80, edetate disodium dihydrate, citric acid anhydrous, benzalkonium chloride and water for injection.

What the medicine looks like and contents of the pack:
Plastic bottles with a dropper and cap. The bottle contains 5 ml of clear, colorless - light yellow solution.

Registration holder's name and address: Fischer Pharma RX Ltd., 7 Hamasger Street, Or Yehuda 6022307

Manufacturer's name and address:
Bausch & Lomb Incorporated
8500 Hidden River Parkway, Tampa, Florida 33637, USA

Registration number of the medicine in the Ministry of Health's National Drug Registry:
177-03-37621-99
Approved in September 2024.

Reference leaflet: FDA leaflet