XALATAN®

Eye Drops

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Xalatan®

Eye Drops

Latanoprost 50 mcg/ml

For a list of inactive and allergenic ingredients in the preparation, please see section 6.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat 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.

This medicine is intended for the treatment of adults over 18 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

For reducing intraocular pressure in patients with open-angle glaucoma and intraocular hypertension.

Therapeutic group: Belongs to the prostaglandin F2 analogue group. It increases the flow of the intraocular fluid into the bloodstream.

2. BEFORE USING THE MEDICINE

☒ Do not use the medicine if:

x You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (listed in section 6).

Special warnings regarding use of the medicine

! Before treatment with Xalatan®, tell the doctor if:

- You are suffering, or have suffered in the past, from eye problems (e.g., eye pain, inflammation, irritation, blurred vision).
- You suffer from dry eyes.
- You suffer from severe asthma or the asthma is not adequately controlled.
- You are about to undergo, or have recently undergone, eye surgery, including surgery for cataract removal.
- You wear contact lenses, you can still use Xalatan®, however, please see directions for using the drops in section 3: "How should you use the medicine?".
- You are suffering, or have suffered in the past, from a viral infection of the eye caused by the herpes simplex virus (HSV).

! If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

In particular, tell the doctor or pharmacist if you know you are using prostaglandins, prostaglandin analogues or prostaglandin derivatives.

! Pregnancy and breast-feeding

Do not use Xalatan® if you are pregnant or breast-feeding, unless your doctor has decided that it is necessary.

If you are pregnant or breast-feeding, think you are pregnant or are planning to become pregnant, inform the doctor before using this medicine.

! Driving and operating machinery

While using Xalatan®, you may temporarily suffer from blurred vision. If this happens to you, **do not drive** or operate dangerous machinery until your vision becomes clear again.

Important information about some of the ingredients of the medicine

! Xalatan® contains benzalkonium chloride (a preservative) and phosphate buffers

Benzalkonium chloride may be absorbed by soft contact lenses and cause their discoloration. Therefore, you should remove them before using this medicine and put them back in after 15 minutes.

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 have an unusual feeling in the eye, stinging or pain in the eye after using the medicine, tell your doctor about it.

If you are suffering from severe damage of the cornea (the clear layer at the front of the eye), phosphates may, in very rare cases, cause cloudy patches on the cornea as a result of accumulation of calcium during the course of treatment.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions! Check with the doctor or pharmacist if you are uncertain. The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is generally: One drop in the treated eye/eyes, once a day, in the evening.

Do not exceed the recommended dose!

Do not use Xalatan® more than once a day, since the efficacy of the treatment decreases if the drops are applied more frequently.

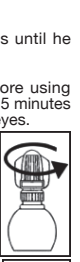
Do not swallow! For external use only.

Use Xalatan® as per your doctor's instructions until he instructs you to discontinue use.

Wearing contact lenses

If you wear contact lenses, remove them before using Xalatan®. After using Xalatan®, you should wait 15 minutes before putting the contact lenses back into the eyes.

Directions for use:



1. Wash your hands and sit or stand comfortably.
2. Twist off the outer cap (which can be thrown away).
3. Unscrew the protective inner cap. The protective cap should be retained.
4. Use your finger to gently pull down the lower eyelid of the treated eye.
5. Place the tip of the bottle close to, but not touching your eye.
6. Squeeze the bottle gently so that only one drop goes into your eye, then release the lower eyelid.
7. Press the corner of the eye, near the nose, with your finger. Hold for about one minute while closing the eye.
8. Repeat the procedure in the other eye, if the doctor has instructed you to do this.
9. Put the inner cap back on the bottle.

If you use Xalatan® together with other eye drops

Wait at least 5 minutes between using Xalatan® and instilling other eye drops.

The bottle of drops may not be full; this is meant to allow for better control of the drip rate.

If you accidentally take a higher dosage

If you instilled more than one drop into the eye, you may experience mild irritation in the eye, and your eyes may tear and get red. These effects are likely to pass, however, if you are worried, consult your doctor.

Contact the doctor as soon as possible if you or your child accidentally swallowed the medicine.

If you forget to take this medicine at the required time, continue treatment with the next dose as planned, but never take a double dose!

If you stop taking the medicine

If you want to stop taking Xalatan®, consult your doctor. Adhere to the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

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

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of the medicine may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Very common side effects (occur in more than 1 in 10 users):

- A gradual change in eye color by increasing the amount of brown pigment in the colored part of the eye known as the iris. If you have mixed-color eyes (blue-brown, grey-brown, yellow-brown, green-brown), it is more likely that this change will happen to you than if you have eyes of one color (blue, grey, green or brown eyes). Any changes in your eye color may take years to develop although it is usually seen within 8 months of treatment. The color change may be permanent and may be more noticeable if you use Xalatan® in only one eye. There appears to be no problems associated with the change in eye color. The eye color change does not continue after Xalatan® treatment is stopped.
- Redness of the eye.
- Eye irritation (a feeling of burning, grittiness, stinging, itching or the sensation of a "foreign body" in the eye). If you experience irritation in the eyes that is severe enough to cause your eyes tear too much, or that makes you consider stopping use of this medicine, refer to your doctor within one week. Your treatment may be reevaluated to ensure that you will continue receiving treatment that is appropriate for your condition.
- A gradual change to eyelashes and the fine hairs around the treated eye. These changes include increased darkness (color), length, thickness and number of your eye lashes. These changes have primarily been seen in people of Japanese origin.

Common side effects (occur in up to 1 in 10 users):

- Irritation or eye surface disruption, eyelid inflammation (blepharitis), eye pain, light sensitivity (photophobia) and conjunctivitis.

Uncommon side effects (occur in up to 1 in 100 users):

- Blurred vision, eyelid swelling, dryness of the eye, inflammation or irritation of the surface of the eye (keratitis), inflammation of the colored part of the eye (uveitis), retinal swelling.
- Skin rash.
- Angina pectoris, awareness of heart beats (pounding heart, palpitations).
- Asthma, shortness of breath (dyspnea).
- Chest pain.
- Headache, dizziness.
- Muscle pain, joint pain.

Rare side effects (occur in up to 1 in 1,000 users):

- Inflammation of the iris (iritis), symptoms of swelling, scratching/damage to the surface of the eye, swelling around the eye (periorbital oedema), an extra row of eyelashes, scarring of the surface of the eye, fluid-filled area in the colored part of the eye (iris cyst).
- Darkening of the skin of the eyelid or eyelid skin reactions.
- Worsening of preexisting asthma.
- Severe itching of the skin.
- Developing a viral infection of the eye caused by the herpes simplex virus (HSV).

Very rare side effects (occur in less than 1 in 10,000 users):

- Worsening of angina in patients who suffer from heart disease, sunken eye appearance (ocular sulcus deepening).

In very rare cases, during treatment, certain patients with severe damage to the anterior part of the eye (cornea) developed cloudy patches on the cornea due to calcium sedimentation.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Before opening:** Store in the refrigerator at a temperature of 2°-8°C, protected from light.
- **After opening:** Store below 25°C. Do not use for more than 4 weeks after first opening the bottle.
- Keep the bottle in the original package in order to protect from light.
- Do not use this medicine if the solution has changed color or has become cloudy.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Disodium phosphate anhydrous, Sodium dihydrogen phosphate monohydrate, Sodium chloride, Benzalkonium chloride, Water for injection.

This medicine contains 0.2 mg benzalkonium chloride per milliliter.

This medicine contains 6.3 mg phosphate per milliliter, which is equivalent to 0.2 mg per drop.

What the medicine looks like and the contents of the package: The package contains 2.5 ml clear liquid.

Manufacturer: Pfizer NV/SA, Puurs, Belgium.

License holder: Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzeliya Pituach 46725.

This leaflet format has been determined by the Ministry of Health and the content thereof has been checked and approved in August 2017 and updated according to the guidelines of the Ministry of Health in January 2019.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 109.36.29264