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

The medicine is dispensed with a doctor's prescription only

Flarex®

Eye drops

Composition: The active ingredient:
Fluorometholone acetate 0.1%

Read this package insert 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 for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Therapeutic activity: Steroidal preparation for treatment of eye inflammations.

Therapeutic group:
Corticosteroid, anti-inflammatory.

2. BEFORE USING THE MEDICINE

☒ Do not use the medicine if:

- you have a known sensitivity to any of the ingredients of the medicine
- you suffer from:
- herpes simplex
- fungal eye diseases
- untreated bacterial infection
- viral eye diseases
- tuberculosis of the eye
- after removal of a foreign lump from the eye that did not cause complication
- eye injury

Special warnings regarding use of the medicine:
Do not use the medicine without consulting the doctor before starting treatment:

- If you are pregnant or breastfeeding.
- If you suffer from eye problems such as: injury of the optic nerve, visual impairment, cataract, any eye infection, intraocular pressure (glaucoma) and diabetes.
- This preparation is intended for use in the eyes only.
- If you experience exacerbation or sudden recurrence of the symptoms – consult the doctor.
- In case of infection – the doctor will prescribe another medicine for you to treat the infection. In case of an infection caused by the herpes simplex virus – consult the doctor.
- Prolonged use may cause a fungal infection of the cornea.
- Do not use this medicine often or for prolonged periods without consulting the doctor.
- When the treatment period exceeds 10 days, perform intraocular pressure measurements; intraocular pressure should be measured on a weekly basis in glaucoma patients.
- Upon prolonged use or use of high dosages, this medicine may reduce the production of the cortisol hormone and cause slowed growth in children.
- This medicine may delay healing of an eye injury.
- If you suffer from a disease causing thinning of eye tissues (cornea or sclera), **Flarex** may cause perforation of the eyeball. Consult the doctor before using the medicine.

! If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. It is especially important to inform the doctor or the pharmacist if you are taking:

- Eye drops given to dilate the pupils (which contain atropine or other anticholinergic agents)
- Medicines to treat glaucoma

If the patient is using other eye drops, wait at least 5 minutes between each application.

! Pregnancy and breastfeeding
Do not use the medicine without consulting a doctor before commencing treatment if you are pregnant, planning to become pregnant or are breastfeeding.

! Children
Use of **Flarex** is not recommended in children below the age of 2. The safety and efficacy in children 2 years of age and below has not been proven.

! Driving and use of machines
Use of this medicine may cause blurred vision and therefore requires that caution be exercised when driving a car, operating machinery and the like.

! Important information regarding some of the ingredients of the medicine
The preparation contains the benzalkonium chloride preservative, which may be absorbed by soft contact lenses. Do not use this preparation when you are wearing soft contact lenses. Remove the lenses before using the preparation and replace them after at least 15 minutes have elapsed from instilling the medicine into the eye.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure. The dosage and treatment regimen will be determined by the doctor only.
Dosage: According to the doctor's instructions only. Do not exceed the recommended dose. If there is no improvement in your condition within 7 days, refer to the doctor. Use this medicine at set intervals, as determined by the attending doctor.
Attention: Do not swallow! This medicine is intended for external use only.

Directions for use:
Shake the bottle well before use.
In order to prevent infection, do not allow the tip of the bottle to touch any surface (including the eye itself). Keep the bottle closed tightly. The bottle of drops may not be full; this is to allow for better control of the drip rate.

How to use the drops: First, wash your hands. Tilt your head back. With the aid of the forefinger, pull the lower eyelid downward, to form a "pocket". Instill the medicine into the "pocket" formed. Close your eyes gently. Do not blink. Keep your eyes closed for 1 to 2 minutes. Immediately after instilling the drops into the eye, press with your middle finger on the inner corner of the eye. Continue pressing for 1 to 2 minutes after applying to the eye. This action helps prevent absorption of the medicine into the body and thereby helps prevent side effects. After using the medicine, wash your hands thoroughly to clean them of any remnants of the medicine. In order to prevent spread of the infection, do not use the same bottle of medicine for more than one person.
If you forget to take this medicine at the designated time, take a dose as soon as you remember; but never take two doses together.
If you instilled more drops of **Flarex** than required into the eye(s), rinse your eyes with lukewarm water. Apply the next dose at the regular time. If you took an overdose or if a child accidentally swallowed the medicine, refer to a doctor or proceed to a hospital immediately and bring the package of the medicine with you.
Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
Adhere to the treatment regimen recommended by the doctor.
Even if there is an improvement in your health, do not discontinue use of this medicine without consulting the doctor or pharmacist.
If you have further questions regarding use of the medicine, ask the doctor or pharmacist.

4. SIDE EFFECTS

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

Eye-related side effects:

Side effects occurring infrequently:
Irritation, redness, increased intraocular pressure

Side effects occurring rarely:
Swelling, itching, dilated pupils, drooping of the eyelid, cataract, glaucoma, development of eye infections or exacerbation of pre-existing infections, impaired vision.

Side effects occurring very rarely:
Perforation of the eye.

Side effects of unknown frequency:
Blurred vision, pain, abnormal sensation and discomfort in the eye, increased tear production.

Side effects relating to other body organs:

Side effects occurring infrequently:
Hypersensitivity, slow healing.

If any of these side effects worsen, or if you suffer from any side effect not listed in this leaflet, consult with the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from 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.
- **Storage:** Store upright, below 25°C.
- Do not use the medicine for more than 28 days from the time the bottle was first opened.
- Close tightly to prevent penetration of air and moisture.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Benzalkonium chloride, disodium edetate, sodium dihydrogen phosphate monohydrate, tyloxapol, sodium chloride, hydroxyethylcellulose, hydrochloric acid, sodium hydroxide, purified water.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
610427349

Manufacturer:
Alcon-Couvreur, Belgium.

License holder:
Lapidot Medical Import and Marketing Ltd.,
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