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

This medicine is dispensed with a doctor's prescription only

FML LIQUIFILM®
Ophthalmic Suspension

Active ingredient
fluorometholone 0.1% w/v

Inactive ingredients and allergens in the medicinal product: 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 to treat your illness/for you. Do not pass it on to others. It may harm them, even if it seems to you that their illness/medical condition is similar to yours.
This medicine is not intended for children below the age of two years.

1. What is this medicine intended for?

FML is used to treat eye inflammation.
Therapeutic group: corticosteroids.

2. Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to the active substance fluorometholone or any of the other ingredients in this medicine (see section 6, 'Additional Information').
- you have a bacterial, viral or fungal eye infection.

Special warnings about using this medicine
Talk to your doctor or pharmacist before using FML.
Do not use FML for more than one week unless your doctor or eye specialist recommends that you do so.
Prolonged use may cause the pressure inside the eye (intraocular pressure) to increase, which could lead to glaucoma, rarely to damage to the optic nerve, lack of clearness of vision, cataracts, delay in the healing of wounds or the development of an eye infection. The intraocular pressure will be regularly measured.
If you are being treated or have previously been treated for herpes simplex, use FML only under your doctor's close supervision.
The use of the bottle by more than one person may lead to a spread of an infection.
Contact your doctor if you experience blurred vision or other visual disturbances.

Children
Safety and efficacy in children aged 2 years or less have not been proven.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:
Certain medicines may increase the effects of FML and your doctor may wish to monitor your treatment if you are using these medicines (including medicines to treat human immunodeficiency virus [HIV]: ritonavir, cobicistat).
If you are using other eye drops, wait at least 5 minutes before using FML.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, consult your doctor or pharmacist before taking this medicine.

Driving and using machines
FML may cause temporary blurred vision. If this occurs, wait for the blurring to clear before driving or operating machinery or taking part in any activity that could put you or others at risk. Caution children against riding a bicycle, playing near a road and similar activities.

Important information about some of this medicine's ingredients

FML contains benzalkonium chloride
Each 1 ml of this medicine contains 0.046 mg of benzalkonium chloride. Benzalkonium chloride may be absorbed by soft contact lenses and change their color. You should remove contact lenses before using this medicine. You may put your contact lenses back in the eyes only after waiting 15 minutes since you used the medicine.

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, consult your doctor.

FML contains phosphates
Each 1 ml of this medicine contains 1.91 mg of phosphates.
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 to appear on the cornea due to calcium build-up during treatment.

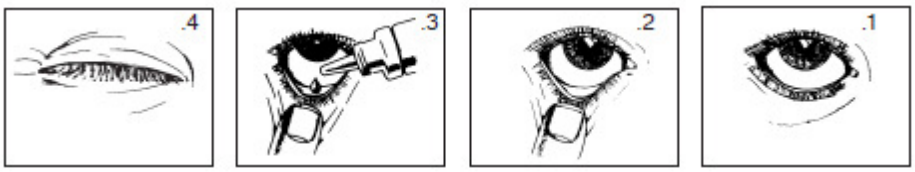
3. How to use this medicine?
Always use the medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.
The usually recommended dosage is 1 or 2 drops of FML in each eye that needs treatment 2-4 times a day, or more frequently if your doctor recommends it. During the first 24-48 hours of treatment, your doctor may advise you to apply 2 drops at one-hour intervals.

Do not exceed the recommended dose.
Do not discontinue treatment too early.

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

Instructions for use
Do not use the bottle if the seal on the bottle neck is broken before your first use.
Shake the bottle before use. Wash your hands before opening the bottle.

Use the eye drops in the following way:



1. Tilt your head back and look at the ceiling.
2. Gently pull down your lower eyelid until there is a small pocket.
3. Turn the bottle upside down and gently squeeze it to release 1-2 drops into your eye.
4. Let go of your lower eyelid and close your eyes for 30 seconds.
5. Repeat steps 2 to 4 for the other eye, if it also needs treatment.

If a drop misses your eye, try again.

To protect the eye drops from contamination and to avoid eye injury, make sure the tip of the bottle does not touch your eye or anything else.
Replace the cap and close the bottle tightly immediately after use.
Wipe off any excess liquid from your cheek with a clean paper tissue.

If you have accidentally taken a higher dose
If you use more drops of FML than needed, this is unlikely to cause you any harm. If you have applied too many drops in your eye(s), wash your eyes with clean water. Apply your next dose at the usual time.

If you accidentally drink FML
If anyone accidentally drinks FML, it is unlikely to cause any harm. The person should drink fluids to dilute.

If you forget to use the medicine
If you forget a dose, use FML as soon as you remember, unless it is almost time for your next dose. Take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose.
Adhere to the treatment as recommended by your doctor.

If you stop taking this medicine
In order for FML to work properly, use it as recommended by your doctor or pharmacist.
Do not take medicines in the dark! Check the label and dose <u>every time</u> 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 FML may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.
The following side effects are known to occur but their frequency can vary, as described.

If you experience swallowing or breathing difficulties, swelling of your lips, face, throat or tongue, immediately contact your doctor, pharmacist or the hospital, because this could be a sign of a serious allergic reaction.
The frequency of an allergic reaction is not known.

Side effects affecting the eye
Common side effects (affect 1-10 in 100 users):
Increased pressure inside the eye

Side effects of unknown frequency (side effects whose frequency has not been established yet):

- Cataract (a loss of transparency of the lens of the eye, with partial or complete loss of vision)
- Eye irritation
- Eye inflammation
- Redness of the eye
- Stinging of the eye
- Eye pain
- A feeling that something is in your eye
- Difficulty seeing clearly
- Swelling of the eyelid or eye
- Drooping eyelid(s)
- Discharge from the eye
- Excessive dilation of the pupil
- Increased production of tears
- Ulcer(s) on the surface of the eye
- Small breaks in the surface of the eye
- Defects in visual field
- Secondary infections (including bacterial, fungal, and viral infections)
- Blurred vision

Side effects affecting the body
Side effects of unknown frequency (side effects whose frequency has not been established yet):
Rash, abnormal sense of taste, allergic reaction (hypersensitivity).

Other side effects reported with eye drops containing phosphates
In very rare cases, some patients with severe injury 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 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.

Reporting side effects
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. 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 a doctor.

Do not use the medicine after the expiry date (exp. date), which is stated on the carton and label. The expiry date refers to the last day of that month.

Storage conditions
Store below 25˚C. Do not freeze.

Do not use this bottle for more than 28 days after opening. To help you remember, write down the date you opened the bottle on the carton.

Keep the container tightly closed to prevent contamination.

Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Polyvinyl alcohol, sodium chloride, sodium phosphate dibasic heptahydrate, edetate disodium, sodium phosphate monobasic monohydrate, polysorbate 80, benzalkonium chloride, sodium hydroxide (for pH adjustment), and purified water.

What the medicine looks like and contents of the pack:
a white suspension supplied in a plastic dropper bottle with a screw cap.
The bottle contains 5 ml of suspension.

Manufacturer: Allergan Pharmaceuticals Ireland, Castlebar Road, Westport, County Mayo, Ireland.

Registration holder's name and address: AbbVie Biopharmaceuticals Ltd., 4 Haharash St., Hod Hasharon, Israel.

Revised in December 2023 according to the Ministry of Health guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 042-55-24101.