

The content of this leaflet was revised according to Ministry of Health instructions

Patient Package Leaflet in Accordance With the Pharmacists’ Regulations (Preparations) - 1986

The medicine is dispensed with a doctor’s prescription only

FML[®] LIQUIFILM[®]
Sterile eye drops, suspension

Active ingredient: Fluorometholone 1 mg/ml

Inactive ingredients and allergens in this medicine: See Section 6 ‘Additional Information’.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it onto others. It may harm them, even if it seems to you that their illness is similar.
This medicine is not intended for use in children under 2 years old.

1. What is this medicine intended for?

FML Liquifilm is an eye drop. It contains a steroid which is used to treat inflammation of the eye.
Therapeutic group: Corticosteroids.

2. Before using this medicine

Do not use this medicine if:

- you are allergic (hypersensitive) to fluorometholone, benzalkonium chloride, or any of the other ingredients that this medicine contains (see Section 6 ‘Additional Information’).
- you have a bacterial, viral, or fungal infection of the eye.

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

Children
The safety and efficacy in children younger than 2 years old have not been shown, therefore this medicine is not intended for this population.

If you are taking, or if you took lately, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
Some medicines may increase the effects of FML Liquifilm and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for an infection caused by human immunodeficiency virus (HIV): ritonavir, cobicistat).
If you are using other eye drops, wait at least 5 minutes before putting in FML Liquifilm.

Pregnancy and breastfeeding
Tell your doctor before you start using FML Liquifilm if you are pregnant or planning to become pregnant or if you are breastfeeding. Your doctor will decide if you should use FML Liquifilm during pregnancy or while breastfeeding. Normally it is not recommended for use.

Driving and using machinery
FML Liquifilm can cause temporary blurred vision. Should this occur, wait for the blurring to clear before driving or operating machinery or taking part in any activity where this could put yourself or others at risk. Children should be warned not to ride a bicycle or play near the road.

Important information about some of this medicine’s ingredients
FML Liquifilm contains benzalkonium chloride as a preservative, which is known to discolor soft contact lenses and can cause eye irritation. If you wear soft contact lenses you must remove them before using FML Liquifilm eye drops and wait at least 15 minutes before putting your lenses back in.

3. How to use this medicine?

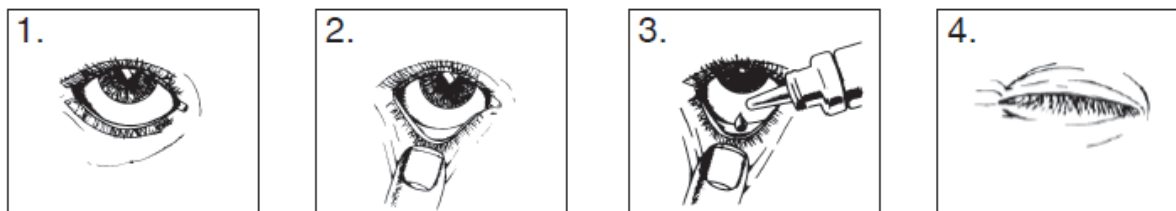
Always use this medicine as instructed by your doctor. Check with your doctor or pharmacist if you are not sure about your dosage or about how to take this medicine. Only your doctor will determine your dosage and how you should take this medicine.
The usual dosage is 1 or 2 drops of FML Liquifilm in each eye that needs treatment 2 to 4 times a day, or more frequently if your doctor advises it. During the first 24 to 48 hours of treatment your doctor may advise you to apply 2 drops at one hour intervals.
Do not exceed the recommended dose.
Treatment should not be withdrawn too early.

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

Instructions for use

You must not use the bottle if the seal on the bottle neck is broken before you first use it.
Shake the bottle before use. Wash your hands before opening the bottle.

Use your eye drops in the following way:



1. Tilt your head back and look at the ceiling.
 2. Gently pull down the lower eyelid until there is a small pocket.
 3. Turn the bottle upside down and gently squeeze it to release 1 or 2 drops into the eye.
 4. Let go of the lower lid, and close your eyes for 30 seconds. Do not blink.
- Immediately after applying the drops into the eye, put pressure on the inner corner of the eye using your middle finger. Keep your eyes closed and continue applying pressure for 1-2 minutes after applying the drops to the eye. This action helps avoid the absorption of the medicine into the body and in this way helps prevent side effects.

Repeat steps 2 to 4 for the other eye, if it also needs treatment.
If a drop misses your eye, try again.

To keep the eye drops free from contamination and avoid eye injury, do not allow the tip of the bottle touch your eye or anything else.
The bottle of drops may not be full. This is meant to allow better control over the drip rate.
Put the cap back on and close the bottle tightly straight after use. Wipe off any excess liquid from your cheek with a clean tissue.
After using the medicine, wash your hands thoroughly in order to wash off remnants of the medicine.
To avoid transmitting infection, do not use the same medicine container for more than one person.

If you accidentally take a higher dosage

If you use more drops of FML Liquifilm than you should, it is unlikely to cause you any harm. If you have placed too many drops in your eye(s), wash your eyes with clean water. Instil your next dose in at the usual time.

If you drink FML Liquifilm by accident

If anyone drinks FML Liquifilm by accident, it is unlikely to cause any harm. The affected person should drink fluids to dilute.

If you forget to use the medicine

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

If you stop taking the medicine

To work properly you must use FML Liquifilm as advised by your doctor or pharmacist.

Do not take medicines in the dark! Check the label and the dose each 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, use of FML Liquifilm may cause side effects in some users. Do not be alarmed by the 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 shown.

Contact your doctor or go to the hospital immediately if you experience swallowing or breathing difficulties, swelling of your lips, face, throat or tongue as 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 (may affect up to 1 in 10 patients):

Increased pressure inside your eye

Side effects of unknown frequency (frequency cannot be estimated from the available data):

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

Itching of the eye

Eye pain

A feeling that something is in your eye
Difficulty in seeing clearly
Swelling of the eyelid or eye
Eye discharge
Excessive dilatation of the pupil
Excessive tear production
Ulcer(s) on the surface of the eye
Small breaks in the surface of the eye
Visual field defects
Secondary infections (including bacterial, fungal, and viral infections)
Blurred vision

Side effects affecting the body

Side effects of unknown frequency (frequency cannot be estimated from the available data):

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 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 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 link 'Reporting side effects of Medication' 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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. How to store this medicine

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of sight and reach of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Store below 25°C. Store in a dark place. Do not freeze.

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

You must throw away the bottle 28 days after you first opened it, even if there are still some drops left. To help you remember, write down the date you opened it on the carton.

Keep the container tightly closed to prevent contamination.

You must not use the bottle if the seal on the bottle neck is broken before you first use it.

Do not discard medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Additional information

In addition to the active ingredient this medicine also contains:

Polyvinyl alcohol, benzalkonium chloride, edetate disodium, sodium chloride, sodium phosphate dibasic heptahydrate, sodium phosphate monobasic monohydrate, polysorbate 80, sodium hydroxide (for pH adjustment), and purified water.

What the medicine looks like and what are the contents of the package:

FML Liquifilm is a white suspension supplied in a plastic dropper bottle with a screw cap. The bottle contains 5 ml of suspension.

Manufacturer: Allergan Pharmaceuticals Ireland, Westport, Ireland.

Registration holder: Allergan Israel Ltd., 32 Shacham st., POB 6869, Petach Tikva 4951727.

This leaflet was reviewed and approved by the Ministry of Health in February 2017 and revised in February 2018 in accordance with Ministry of Health guidelines.

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

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