

**FML™****LIQUIFILM™ 0.1% w/v STERILE EYE DROPS SUSPENSION**
(Fluorometholone)

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.

In this leaflet:

1. What FML is and what it is used for
2. Before you use FML
3. How to use FML
4. Possible side effects
5. How to store FML
6. Further information

1. WHAT FML IS AND WHAT IT IS USED FOR

FML is an eye drop. It contains a steroid which is used to treat inflammation of the eye.

2. BEFORE YOU USE FML**Do not use FML**

- if you are allergic (hypersensitive) to fluorometholone, benzalkonium chloride, or any of the other ingredients of FML.
- if you have a bacterial, viral, or fungal infection of the eye.

Take special care with FML

You should not use FML for more than one week unless your doctor or eye specialist advises it. Prolonged use may cause glaucoma (increased pressure inside the eye), thinning of or a hole in the surface of the eye, cataracts, or the development of an eye infection. The pressure in your eye will be regularly measured.

If you have a red eye this may be caused by herpes simplex virus, and FML may make the inflammation worse. Talk to your doctor or pharmacist before using FML.

If your skin is thinning and fine red lines and enlarged blood vessels are appearing, especially on your face.

Using other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, even those obtained without a prescription.

If you are using other eye drops, leave at least 5 minutes before putting in FML.

Children

The safety and effectiveness in children aged 2 years or less have not been shown.

Pregnancy and breast feeding

Tell your doctor before you start using FML if you are pregnant or planning to become pregnant or if you are breast feeding. Your doctor will decide if you should use FML during pregnancy or whilst breast feeding. Normally it is not recommended for use.

Driving and using machines

FML can cause temporary blurred vision. Should this occur, wait for the blurring to clear before driving or operating machinery.

Important information about some of the ingredients of FML

FML contains benzalkonium chloride as a preservative, which is known to discolour soft contact lenses and can cause eye irritation. If you wear soft contact lenses you must remove them before using FML eye drops and wait at least 15 minutes before putting your lenses back in.

Ask your doctor or pharmacist for advice before using any medicine.

3. HOW TO USE FML

Always use FML exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is 1 or 2 drops of FML 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.

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 this eye 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 keep the eyedrops free from contamination, do not let the tip of the bottle touch your eye or anything else. 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.



If you use more FML than you should

If you use more drops of FML 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. Put your next dose in at the usual time.

If you drink FML by accident

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

If you forget to use FML

If you forget a dose, use FML 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.

If you stop using FML

To work properly FML should be used as advised by your doctor or pharmacist.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, FML can have side effects, although not everybody gets them. The following side effects are known to occur but their frequency can vary as shown. If you experience swallowing or breathing difficulties, swelling of your lips, face, throat or tongue contact your doctor or go to the hospital immediately as this could be a sign of a serious allergic reaction. The frequency of an allergic reaction is not known.

Affecting the eye

Frequency - Common (affecting up to 1 in 10 patients):

Increased pressure inside your eye

Frequency not known:

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

Abnormality of the surface of the eye

Excessive dilatation of the pupil

Excessive tear production

Affecting the body

Frequency not known:

Rash, abnormal sense of taste, headache, dizziness, raised blood pressure.

If any of the side effects get serious, or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE FML

Keep out of the reach and sight of children.

Do not use an unopened bottle of FML after the expiry date which is stated on the bottle label and on the carton after "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C. Do not refrigerate or freeze.

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 in the space provided on the carton. Keep the container tightly closed to prevent contamination.

Medicines should not be disposed of 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. FURTHER INFORMATION

What FML contains

The active substance is fluorometholone 1 mg/ml.

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

What FML looks like and contents of the pack

FML is a white suspension supplied in a plastic dropper bottle with a screw cap.

The bottle contains 5 ml or 10 ml of suspension.

Marketing Authorisation Holder and Manufacturer

Allergan Pharmaceuticals Ireland

Castlebar Road

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Co. Mayo

Ireland

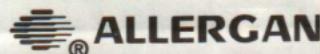
This leaflet was last approved on 8th December 2008

(THIS IS A MEDICAMENT)

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists



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