

FML® LIQUIFILM® STERILE OPHTHALMIC SOLUTION

fluorometholone (0.1% w/v)

What is in this leaflet

1. What FML® LIQUIFILM® is used for
2. How FML® LIQUIFILM® works
3. Before you use FML® LIQUIFILM®
4. How to use FML® LIQUIFILM®
5. While you are using it
6. Side effects
7. Storage and Disposal of FML® LIQUIFILM®
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What FML® LIQUIFILM® is used for

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

How FML® LIQUIFILM® works

FML® LIQUIFILM® is a steroid medicine. It prevents the release of substances in the body that cause inflammation.

Before you use FML® LIQUIFILM®

- When you must not use it

Do not use FML® LIQUIFILM®:

- If you are allergic (hypersensitive to fluorometholone, benzalkonium chloride, or any of the other ingredients of FML® LIQUIFILM®. (for a full list of ingredients, see section "PRODUCT DESCRIPTION").
- if you have a bacterial, viral, or fungal infection of the eye

- Pregnancy and lactation

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 whilst breastfeeding.

- Children

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

- Before you start use it

Take special care with FML® LIQUIFILM®.

Prolonged use may cause glaucoma (increased pressure inside the eye), affects vision, thinning or clouding of or a hole in the surface of the eye, development of an eye infection, secondary eye infections or exacerbate existing eye infection.

Talk to your doctor or pharmacist before using FML® LIQUIFILM®.

- Taking other medicines

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

Some medicines may increase the effects of FML and your doctor may wish to monitor you carefully.

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use FML® LIQUIFILM®

- How much to use

1 to 2 drops instilled into the eye two to four times daily. During the initial 24 to 48 hours the dosage may be safely increased to 2 drops every hour. Care should be taken not to discontinue therapy prematurely.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not

understand the instructions on the label, ask your doctor or pharmacist for help.

- 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 eye for 30 seconds.



5. Repeat steps 2 to 4 for the other eye, if it also needs treatment.

To keep the eye drops 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. - <u>When to use it</u> Use as directed by your doctor or pharmacist. - <u>How long to use it</u> Continue taking FML® LIQUIFILM® for as long as your doctor recommends. Eye drops containing steroids should not be used for more than 10 days except strict eye specialist supervision with regular checks for the pressure in your eye - <u>If you forget to use it</u> Consult your doctor or pharmacist on what you should do if you forget to use it. Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose. - <u>If you use too much (overdose)</u> 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. Put your next dose in at the usual time. If you have accidentally ingested FML® LIQUIFILM®, drink fluids to dilute.	While you are using it - <u>Things you must do</u> Take your medicine exactly as your doctor has told you. Tell all the doctors, dentists and pharmacists treating you that you are taking FML® LIQUIFILM®. Tell your doctor immediately if you become pregnant while taking this medication. Intraocular pressure (pressure inside your eye) should be checked frequently. - <u>Things you must not do</u> Do not stop taking the medicine unless advised by your doctor. Do not take any new medicines without consulting your doctor. Do not give FML® LIQUIFILM® to anyone else, even if they have the same symptoms or condition as you. - <u>Things to be careful of</u> <i>Driving and using machines:</i> FML® LIQUIFILM® can cause temporary blurred vision. Should this occur, wait for the blurring to clear before driving or operating machinery. <i>Using contact lenses:</i> FML® LIQUIFILM® 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® LIQUIFILM® eye drops and wait at least 15 minutes before putting your lenses back in. Side effects Like all medicines, FML® LIQUIFILM® can cause side effects, although not everybody gets them.	- Increased pressure inside your eye which may lead to glaucoma, and infrequent eye nerve damage - cataract (clouding of the lens of the eye with partial or complete loss of vision) - visual disturbance - hole in the eye - delayed wound healing - eye irritation, eye pain, red eye, a feeling that something is in your eye - itchy eyes, watery eyes, eye swelling - eyelid swelling - enlarged pupil - eye ulcer, eye infection, inflammation of the surface of the eye - damage to the surface of the eye - allergic reaction - change in sense of taste and rash. - eyelid drooping (<i>eyelid ptosis</i>) - corneal calcification Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website nppra.gov.my [Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]. Storage and Disposal of FML® LIQUIFILM® - <u>Storage</u> Keep out of the reach and sight of children. Protect from freezing. Store upright. On prescription only. Shake well before use. Do not use FML® LIQUIFILM® after the expiry date which is stated on the bottle label and the bottom of the carton after EXP. Store below 30°C - <u>Disposal</u>
---	--	---

Discard unused contents 4 weeks after opening.

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.

Product Description

- What it looks like

FML® LIQUIFILM® is a white suspension supplied in a plastic dropper bottle.

The bottle contains 5 ml or 10 ml of suspension.

Not all pack sizes may be marketed.

- Ingredients

- Active ingredient
fluorometholone
- Inactive ingredients
liquifilm (polyvinyl alcohol),
benzalkonium chloride, edetate
disodium, sodium chloride, sodium
phosphate monobasic, sodium
phosphate dibasic, polysorbate 80,
sodium hydroxide and purified water

- MAL number:

MAL19890344ARZ

Manufacturer

Allergan Pharmaceuticals Ireland
Castlebar Road
Westport
County Mayo
Ireland

Product Registration Holder

ABBVIE SDN BHD
9th Floor Menara Lien Hoe
No.8, Persiaran Tropicana
Tropicana Golf & Country Resort
47410 Petaling Jaya Selangor, Malaysia

Date of revision

27/02/2024

Serial Number

NPRA (R1/2) 26022024/038