Clean Copy Patient Information Leaflet

SCHEDULING STATUS

Schedule 4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

FML® Liquifilm® Sterile Eye Suspension, fluorometholone 0,1 %

Read all of this leaflet carefully before you start using FML®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- FML® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT FML® CONTAINS

- The active substance in FML® is fluorometholone 1,0 mg/ml.
- It contains benzalkonium chloride 0,004 % m/v as a preservative.
- The other inactive substances are Liquifilm® (polyvinyl alcohol) 14 mg/ml, edetate disodium, polysorbate 80, sodium phosphate dibasic heptahydrate, sodium phosphate monobasic monohydrate, sodium chloride and purified water.

2. WHAT FML® IS USED FOR

FML® contains fluorometholone, a steroid that reduces irritation, burning, redness and swelling of eye inflammation.

FML® is used to treat eye inflammation in certain parts of the eye.

3. BEFORE YOU USE FML®

Do not use FML®:

- If you are hypersensitive (allergic) to fluorometholone, benzalkonium chloride or any of the other ingredients of FML®;
- If you are suffering from viral, fungal or severe bacterial eye infection or tuberculosis of the eye. Please also tell your doctor if you have a history of these conditions.

Take special care with FML®

Tell your doctor:

- If you have ever suffered from any other eye problem, particularly infection, that required treatment from a doctor or specialist;
- If you are pregnant or breastfeeding;
- If you wear soft (hydrophilic) contact lenses. (The preservative benzalkonium chloride can permanently damage this type of lens.)

Prolonged use may cause the pressure inside your eye (intraocular pressure) to increase which could lead to glaucoma, 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 have or have been previously treated for herpes simplex, use FML only under close supervision of your doctor.

The safety and effectiveness in children under 2 years of age have not been established.

You should not use FML® for longer than 10 days except when your doctor is regularly checking the pressure within your eye.

If you develop any kind of corneal (see-through layer covering the eye) disease, immediately inform your doctor.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using FML®.

The safety of FML® during pregnancy and breastfeeding has not been established. FML® is therefore not recommended for mothers who are breastfeeding.

Driving and using machinery

You may experience transient blurred vision after instillation of FML® drops. You should wait until your vision clears before driving or using machinery.

Important information about some of the ingredients of FML®

FML® is preserved with benzalkonium chloride. You should undergo regular eye examinations if you are using FML® for a prolonged period of time. Benzalkonium chloride may cause side effects on your corneal permeability with prolonged or repeated use.

Contact lenses:

- Do not use the drops while your contact lenses are in your eyes. Wait at least 15 minutes after using the eye drops before putting your lenses back in your eyes.
- Benzalkonium chloride, the preservative in FML® may cause eye irritation and is also known to discolour soft contact lenses.

Using other medicines with FML®

Always tell your healthcare professional if you are taking any other medicines. (This includes complementary or traditional medicines.)

4. HOW TO USE FML®

Do not share medicines prescribed for you with any other person.

Always use FML® exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is one to two drops of FML® instilled into the eye two to four times daily.

FML® should not normally be used for longer than 10 days without review by your doctor.

During the first two days of treatment you may be asked to apply the drops every hour.

Do not use FML® more or less often, or for a longer period, than you are told to by your doctor or pharmacist. Do not stop using FML® until your doctor tells you to.

If you have the impression that the effect of FML® is too strong or too weak for you, tell your doctor or pharmacist.

How to use FML®

FML® comes as eye drops. Your prescription label tells you how many drops to use at each dose.

Apply your eye drops in the following way:

1.  Tilt your head back and look upward.	2.  Gently pull the lower eyelid down until there is a small pocket.	3.  Squeeze the upturned dropper bottle to release a drop into your eye.	4.  Release the lower lid and close your eye for 30 seconds.

To prevent injury or contamination, avoid touching the dropper tip against your eye or anything else.

Replace and tighten the cap straight after use.

The proper application of your eye drops is very important.

If you have any questions ask your doctor or pharmacist.

If you use more FML® than you should

If you accidentally place too many drops in your eye(s), wash the eye(s) with water. The application of too many drops is, however, unlikely to lead to unwanted side effects.

If you accidentally ingest the medicine, drink fluids to dilute it.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use FML®

If you forget to apply a dose, apply it as soon as you remember and then apply any remaining doses for that day at evenly spaced intervals. If, however, it is almost time for your next dose, you should omit the missed dose altogether and then follow your normal routine.

Do not apply a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

FML® can have side effects. Not all side effects reported for FML® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using FML®, please consult your doctor, pharmacist or other healthcare professional for advice.

You may experience mild stinging and/or burning when the drops are applied and temporary blurred vision.

If you experience pressure or pain in the eye you should see your doctor at once.

The following side effects have also been reported:

- Eye irritation
- Blurred or reduced vision
- Abnormal sensation in the eye
- Eye pain, increased fluid pressure in the eye including a disease called glaucoma
- Eye and/or eyelid swelling/puffiness
- Eye discharge
- Itching and/or redness of the eye
- An excess of tears
- Eye infection
- Ulcers on the surface of the eye
- Small grey bumps on the surface of the eye
- Excessive dilation of the pupil
- Allergic reactions
- Change in your sense of taste
- Rash

Reporting of side effects

If you get side effects, talk to your doctor. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of FML Liquifilm Sterile Eye Suspension.

In case of a side effect, please contact MEAPV@abbvie.com

6. STORING AND DISPOSING OF FML®

- Store at or below 25 °C. Do not freeze.
- Store in an upright position.
- Store all medicines out of reach of children.
- Do not use the product after the expiry date. This is the date printed on the label of the bottle and on the bottom of the outer carton.
- Do not use the product for longer than 30 days after opening, even if there is solution remaining.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF FML®

FML® Sterile Eye Suspension is supplied in sterile dropper bottles containing 5 ml suspension.

8. IDENTIFICATION OF FML®

A white, microfine suspension.

9. REGISTRATION NUMBER

J/15.2/327

10. NAME AND ADDRESS OF REGISTRATION HOLDER

AbbVie (Pty) Ltd

Building 7, Waterfall Corporate Campus

74 Waterfall Drive

Waterfall City

Midrand, 1685

South Africa

Tel: +27 11 031 1600

11. DATE OF PUBLICATION

Date of registration: 5 August 1977

Date of revision of patient information leaflet: 21 April 2023

Access to the corresponding Professional Information

For the professional information please email medicalinfo.za@abbvie.com

CCDS v4.0 and v5.0