5. How to store FML

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated after EXP on the carton. The expiry date refers to the last day of that month.

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

Once opened discard this bottle after 28 days. 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.

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

6. Contents of the pack and other information

What FML contains
The active substance is fluorometholone 1 mg/ml.

The other ingredients are polyvinyl alcohol, benzalkonium chloride, edetate disodium, sodium chloride, disodium phosphate heptahydrate, sodium dihydrogen phosphate 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. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
AbbVie Ltd.
Maidenhead
SL6 4UB
UK

Manufacturer:
Allergan Pharmaceuticals Ireland
Castlebar Road
Westport
County Mayo
Ireland

This leaflet was last revised in June 2023.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only).
Please be ready to give the following information: Fluorometholone 1 mg/ml reference number PL 41042/0065.
This is a service provided by the Royal National Institute of Blind People.

abbvie

20079206

abbvie

Package leaflet:
Information for the user

FML® LIQUIFILM®

OPHTHALMIC 1 mg/ml
EYE DROPS SUSPENSION
Fluorometholone

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, your pharmacist or your nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet:

1. What FML is and what it is used for
2. What you need to know before you use FML
3. How to use FML
4. Possible side effects
5. How to store FML
6. Contents of the pack and other information

1. What FML is and what it is used for

FML Liquifilm Ophthalmic suspension is an eye drop and contains the active substance fluorometholone which is used to treat inflammation of the eye.

2. What you need to know before you use FML

Do not use FML:
- if you are allergic (hypersensitive) to fluorometholone or any of the other ingredients of this medicine (listed in section 6).
- if you have a bacterial, viral, or fungal infection of the eye.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using FML.

You should not use FML for more than one week unless your doctor, pharmacist, nurse 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 have or have been previously treated for herpes simplex, use FML only under close supervision of your doctor, pharmacist or nurse.

The use of the bottle by more than one person may spread infection.

Contact your doctor, pharmacist or nurse if you experience blurred vision or other visual disturbances.

Other medicines and FML
Tell your doctor, pharmacist or nurse if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription.

Some medicines may increase the effects of FML and your doctor, pharmacist or nurse may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

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.

ARTWORK TEMPLATE
0106901

Colors:
Black
Keyline

abbvie	**File Upload Date:** 08 Jun 2023 14:08 UTC	**Version Number:** 3	**Artwork is created at 100%**
Brief ID: PROD-2023-000516	**New Control Number:** 20079206	**New External Control Number:** N/A	
PDS: N/A	**Size or Drawing Number:** N/A		**LAGN Drawing:** 0106901
Braille Code: N/A	**Packaging Barcode Type:** n/a	**Packaging Barcode Number:** n/a	
Variable Data Required: No			
Comments: • Total pages: 2 • Drop dieline, swatches and artblock before processing. • Smallest Body text size: 9 pt • Vendor allowed to add printer marks, as necessary.			

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine.

Driving and using machines
FML 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.

FML contains Benzalkonium chloride

This medicine contains 0.046 mg benzalkonium chloride in each 1 ml

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

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, talk to your doctor, pharmacist or nurse.

FML Contains Phosphates
This medicine contains 1.91 mg phosphates in each 1 mL
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 on the cornea due to calcium build-up during treatment.

Ask your doctor, pharmacist or nurse for advice before taking any medicine.

3. How to use FML

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The recommended 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, pharmacist or nurse advises it. During the first 24 - 48 hours of treatment your doctor, pharmacist or nurse may advise you to apply 2 drops at one hour intervals.

Treatment should not be withdrawn too early.

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. 
2. 
3. 
4. 

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.

If a drop misses your eye, try again.

To keep the eye drops free from contamination and avoid eye injury, 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, pharmacist or nurse.

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

4. Possible side effects

Like all medicines, this medicine can cause 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, pharmacist or nurse 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

Common (may affect up to 1 in 10 people)
Increased pressure inside your eye

Not known (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
Drooping eyelid(s)
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

Affecting the body

Not known (frequency cannot be estimated from the available data):
Rash, abnormal sense of taste, allergic reactions (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.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard
By reporting side effects you can help provide more information on the safety of this medicine.

ARTWORK TEMPLATE
0106901

Colors:
Black
Keyline

abbvie

	File Upload Date: 08 Jun 2023 14:08 UTC	**Version Number:** 3	**Artwork is created at 100%**
Brief ID: PROD-2023-000516	**New Control Number:** 20079206	**New External Control Number:** N/A	
PDS: N/A	**Size or Drawing Number:** N/A		**LAGN Drawing:** 0106901
Braille Code: N/A	**Packaging Barcode Type:** n/a	**Packaging Barcode Number:** n/a	
Variable Data Required: No			

Comments: • Total pages: 2
• Drop dieline, swatches and artblock before processing.
• Smallest Body text size: 9 pt
• Vendor allowed to add printer marks, as necessary.