
PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

FML-NEO Liquifilm Ophthalmic Suspension 1,0 mg/ml + 5 mg/ml

Fluorometholone and neomycin

Read all of this leaflet carefully before you start using FML-NEO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- FML-NEO 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.

What is in this leaflet

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

1. What FML-NEO is and what it is used for

FML-NEO is used for the treatment of conjunctivitis (sticky eyes) due to organisms sensitive to neomycin.

FML-NEO may be used for the treatment of infections at the front of the eye by bacteria sensitive to the antibiotic neomycin.

FML-NEO can be used following removal of something from your eye, as well as before and after surgery, where there is a possibility of infection with susceptible organisms.

2. What you need to know before you use FML-NEO

Do not use FML-NEO:

- If you are hypersensitive (allergic) to fluorometholone or neomycin sulfate or to any of the other ingredients of FML-NEO listed in section 6. If you experience an allergic reaction, please inform your doctor.
- If you have an eye infection (with pus) caused by micro-organisms not sensitive to the antibiotic neomycin;
- If you have an active viral or fungal infection of the eye;
- If you have tuberculosis of the eye;
- If you have glaucoma;
- If you are pregnant or breastfeeding.

Warnings and precautions

FML-NEO should not be used for more than one week except if your doctor advises you to do so.

If you use FML-NEO for a long period of time:

- It may cause the pressure inside your eye (intraocular pressure) to increase which can lead to glaucoma. The pressure in your eye should be regularly measured.
 - It may cause cataracts (cloudy lens), lack of clearness of vision, or a delay in wound
-

healing of the eye.

- Damage to the front part of the eye (due to a fungal infection), may occur during or after the use of FML-NEO.
- It may increase the risk of corneal damage, cause thinning of the cornea or small ulcerations in the surface of your eye.
- It may also suppress the body's immune response which leads to secondary eye infections.

Children

The safety and efficacy in children aged 2 years or younger has not been established.

Other medicines and FML-NEO

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using FML-NEO.

FML-NEO should not be used during pregnancy and breastfeeding. It is unknown whether the active ingredients of FML-NEO are excreted in breastmilk. FML-NEO is therefore not recommended for mothers who are breastfeeding.

Driving and using machines

FML-NEO may cause temporary blurred vision. If this occurs, you should wait until your vision

becomes clear before driving or using machines.

FML-NEO contains benzalkonium chloride

FML-NEO contains benzalkonium chloride as preservative. It may discolour soft contact lens and may cause eye irritation. 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 lenses back in your eyes. Regular eye examination is required during prolonged and repeated use as the preservative benzalkonium chloride can cause damage to your eyes.

3. How to use FML-NEO

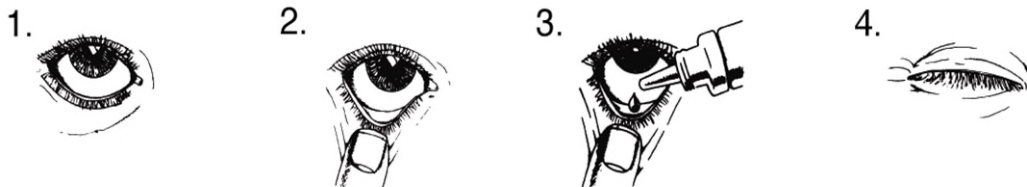
Do not share medicines prescribed for you with any other person.

Always use FML-NEO exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose for adults is: One to two drops in eye two to four times a day. During the first 24 to 48 hours, the dose may be safely increased to one drop every hour or as directed by your doctor. Complete the course of treatment.

Instructions for use

You must not use the bottle if the tamper-proof seal on the bottle neck is broken before you first use it. Apply your eye drops in the following way:



1. Wash your hands. Shake the bottle well before use. Tilt your head back and look at the

ceiling.

2. Gently pull the lower eyelid down until there is a small pocket.
3. Turn the bottle upside down and squeeze it to release one or two drops into each eye that needs treatment.
4. Let go of the lower lid, and close your eye. Press your finger against the corner of your eye (the side where your eye meets your nose) for one minute.

If a drop misses your eye, try again.

To avoid contamination, do not let the tip of the dropper touch your eye or anything else. Replace and tighten the cap straight after use. Wipe off any excess liquid from your cheek with a clean tissue. Do not swallow. The proper application of your eye drops is very important.

Your doctor will tell you how long your treatment with FML-NEO will last. Do not stop treatment early.

If you have the impression that the effect of FML-NEO is too strong or too weak, ~~talk to~~ tell your doctor or pharmacist.

If you use more FML-NEO than you should

If you place accidentally too many drops in your eye, flush the eye with water or saline solution. Apply your next dose at the normal time. If by accident, anyone drinks this medicine, contact your doctor straight away.

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

If you forget to use FML-NEO

Do not use a double dose to make up for the forgotten individual doses. Use a single dose as soon as you remember, unless it is almost time for your next dose. Then apply your next dose as usual and continue with your normal routine.

4. Possible side effects

FML-NEO can have side effects. Not all side effects reported for FML-NEO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using FML-NEO, please consult your health care provider for advice.

The following side effects may occur:

Increased eye pressure (glaucoma), loss of part of the usual field of vision, blurred vision, cataracts (cloudy lens), eye irritation, red eye, eye pain, foreign body sensation, eyelid or eye swelling, droopy eyelid, itchy or watery eye, ulcers on the surface of the eye, secondary eye infections from fungi or viruses, skin rash, allergic reactions, change in your sense of taste.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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-NEO.

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

5. How to store FML-NEO

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C. Do not freeze.

Do not use the medicine after the expiry date printed on the bottle and the box.

Do not use the product if the safety seal placed on the cap of the bottle is broken.

Do not use 30 days after first opening the bottle, even if there is still some liquid remaining.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What FML-NEO contains

- The active substances of FML-NEO are fluorometholone 1,0 mg/ml and neomycin sulfate (equivalent to 3,5 mg neomycin base) 5,0 mg/ml.
- The other ingredients are benzalkonium chloride 0,004 % m/v (as a preservative), Liquifilm (polyvinyl alcohol), disodium edetate, sodium phosphate dibasic heptahydrate, sodium chloride, sodium thiosulfate pentahydrate, polysorbate 80, purified water. Small amounts of hydrochloric acid or sodium hydroxide may be added to bring the suspension to the correct pH level.

What FML-NEO looks like and contents of the pack

FML-NEO is a white to slightly straw coloured, microfine suspension. FML-NEO is supplied in sterile dropper bottles containing 5 ml suspension. A safety seal is placed around the bottle cap to ensure integrity of the product.

Holder of Certificate of Registration

AbbVie (Pty) Ltd

Building 7, Waterfall Corporate Campus

74 Waterfall Drive

Waterfall City

Midrand, 1685

South Africa

Tel: +27 11 031 1600

This leaflet was last revised in

03 September 2024

Registration Number

J/15.2/335

Access to corresponding Professional Information

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