PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

FML-NEO™ Liquifilm Ophthalmic Suspension, fluorometholone 1,0 mg/ml and neomycin sulfate (equivalent to 3,5 mg neomycin base) 5 mg/ml

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 or pharmacist.
- 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.

1. 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 (10 % solution), purified water.

2. WHAT FML-NEO™ 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.

3. 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 "WHAT FML-NEO™ CONTAINS". 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.

Take special care with FML-NEO™:
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.

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

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-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 machinery
FML-NEO™ may cause temporary blurred vision. If this occurs, you should wait until your vision becomes clear before driving or using machines.

Important information about some of the ingredients of FML-NEO™:
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.

Using other medicines with FML-NEO™

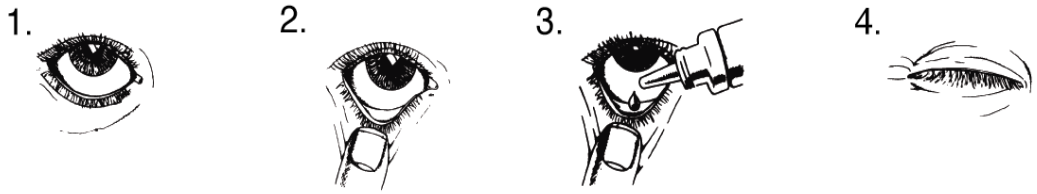
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

4. 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 instructed you. You should check with your doctor or pharmacist if you are unsure.

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 your doctor or pharmacist.

If you have 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 overdosage, 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.

5. 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 doctor, pharmacist or other healthcare professional 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, 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.

6. STORING AND DISPOSING OF 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).

7. PRESENTATION OF FML-NEO™

FML-NEO™ Liquifilm Ophthalmic Suspension is supplied in sterile dropper bottles containing 5 ml suspension. A safety seal is placed around the bottle cap to insure integrity of the product.

8. IDENTIFICATION OF FML-NEO™

FML-NEO™ Liquifilm Ophthalmic Suspension is a white to slightly straw coloured, microfine suspension.

9. REGISTRATION NUMBER/REFERENCE NUMBER

J/15.2/335

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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