

## FML® EYE DROPS

[fluorometholone 1 mg/mL]

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about FML® eye drops, (including how to use the eye drops). It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using FML® eye drops against the benefits they expect it will have for you.

If you have any concerns about using/taking this medicine, ask your doctor or pharmacist.

**Keep this leaflet with the medicine.** You may need to read it again.

#### What FML® eye drops are used for

FML® eye drops are used for the treatment of pain, swelling and redness of the eye (inflammation).

The active ingredient in FML® eye drops, fluorometholone, acts by inhibiting the inflammation caused by certain irritations in the eye.

FML® eye drops are only available with a doctor's prescription from pharmacies.

Your doctor may have prescribed FML® eye drops for another reason. Ask your doctor if you have any questions about why FML® eye drops have been prescribed for you.

#### Before you use FML® eye drops

##### When you must not use it

Do not use FML® eye drops if:

- you are suffering from certain medical conditions such as herpes simplex keratitis
- you have an eye infection caused by fungi or viruses
- you have an allergy to FML® eye drops or any of the ingredients listed at the end of this leaflet
- you have tuberculosis of the eye
- the seal around the cap is broken
- the bottle/packaging shows signs of tampering
- the product does not look quite right.
- the expiry date on the bottle or carton has passed

If you use this medicine after the expiry date has passed, it may not work effectively.

Do not put the eye drops into your eye(s) while you are wearing soft contact lenses. The preservative in FML® eye drops (benzalkonium chloride) may be absorbed by and cause discolouration of soft contact lenses. You can put your soft contact lenses back into your eyes 15 minutes after you have used FML® eye drops.

The safety of FML® eye drops in children under 2 years of age is not known. Therefore these drops should not be used in very young children.

These eye drops are for topical use only.

If you are not sure whether you should start using FML® eye drops, talk to your doctor.

##### Before you start to use it.

Tell your doctor if

1. you have had an allergy to any other medicines or any other substances, such as foods, preservatives or dyes.
2. you have ever had herpes simplex keratitis or have glaucoma.
3. you have recently had an eye infection.
4. you are pregnant or have the intention of becoming pregnant. Safety of the use of topical steroids during pregnancy has not been established.
5. you are breastfeeding or planning to start breastfeeding. It is not known whether your baby may absorb this medicine from breast milk and therefore there is a possibility of harm to the baby.

If you have not told your doctor about this, tell them before you use FML® eye drops.

##### Taking other medicines

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

There are no known drug interactions with FML® eye drops.

#### How to use FML® eye drops

##### How much to use

Your doctor will tell you how many drops you need to use each day. Use FML® eye drops only as prescribed by your doctor.

The usual dosage of FML® eye drops is one to two drops in the affected eye(s) two to four times daily. During the first 24 to 48 hours, your doctor may advise to increase the dosage to 2 drops every hour.

Do not stop using FML® eye drops even if you feel well unless instructed by your doctor.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

Use FML® eye drops every day, at about the same time each day, unless your doctor tells you otherwise. Using your eye drops at the same time each day will have the best effect on your condition. It will also help you remember when to use the eye drops.

If you are using more than one eye drop product, wait 5 minutes before using the second product.

If you are being changed from one eye drop to another, follow your doctor's instructions carefully as to when to stop the old drops and when to start the new drops.

##### How to use it

You may find it easier to put drops in your eye while you are sitting or lying down.

**If you are wearing soft contact lenses, remove them before putting the drops in your eye.**

To open a new bottle of FML® eye drops, first tear off the protective seal from the bottle.

The contents are sterile if the seal is intact.

The seal will break and you can pull it off and then throw it away.

1. Wash your hands well with soap and water.
2. Shake the bottle gently.
3. Remove the cap.

4. Hold the bottle upside down in one hand between your thumb and forefinger or index finger.
5. Using your other hand, gently pull down your lower eyelid to form a pouch or pocket.
6. Tilt your head back and look up.
7. Put the tip of the bottle close to your lower eyelid. Do not let it touch your eye.
8. Release one drop into the pouch or pocket formed between your eye and eyelid by gently squeezing the bottle.
9. Close your eye. Do not blink or rub your eye.
10. While your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to stop the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body. Ask your doctor for more specific instructions on this technique.
11. Replace the cap, sealing it tightly.
12. Wash your hands again with soap and water to remove any residue.

Wait 15 minutes before replacing your contact lenses.

Be careful not to touch the dropper tip against your eye, eyelid or anything else to avoid contaminating the eye drops. Contaminated eye drops may give you an eye infection.

##### How long to use it

Continue using FML® eye drops for as long as your doctor prescribes.

##### If you forget to use it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Otherwise, use the drops as soon as you remember, and then go back to using/taking them as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not use double the amount to make up for the dose that you missed.

##### If you use too much (overdose)

If you accidentally put several drops in your eye(s), immediately flush your eye(s) with water.

If you think that you or anyone else may have swallowed any or all of the contents of a bottle of FML® eye drops, immediately telephone your doctor or **Poisons Information Centre (telephone 13 11 26)** for advice, or go to casualty at your nearest hospital. In New Zealand call the **National Poisons Information Centre (telephone 0800 POISON or 0800 764 766).**

Do this even if there are no signs of discomfort or poisoning.

#### While you are using FML® eye drops

##### Things you must do

If you develop an eye infection, receive an eye injury, or have eye surgery tell your doctor.

Your doctor may tell you to use a new container of FML® eye drops because of possible contamination of the old one, or may advise you to stop your treatment with FML® eye drops.

If you become pregnant while using FML® eye drops tell your doctor immediately.

If you wear soft contact lenses, remove them before using FML® eye drops. Leave your lenses out for at least 15 minutes after putting in the eye drops.

Tell your doctor if your condition gets worse or does not get better while using FML® eye drops.

Tell your doctor if you experience any blurred vision or any other disturbances in vision.

If you are about to start on any new medicine tell your doctor and pharmacist that you are using FML® eye drops.

### **Things you must not do**

Do not give FML® eye drops to anyone else, even if they have the same condition as you.

Do not stop using FML® eye drops without first talking to your doctor.

### **Things to be careful of**

Your vision may blur for a short time after you put in your FML® eye drops. If this happens you should wait until you can see well again before you drive or use machinery.

FML® eye drops are not expected to cause any problems with your ability to drive a car or operate machinery. However, as a general precaution be careful when driving or operating machinery until you know how FML® eye drops affect you.

Eye drops containing a corticosteroid should not be used for more than 10 days except under ophthalmic supervision with regular checks for increased pressure in the eye.

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## **Side effects**

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using FML® eye drops.

FML® eye drops help most people with inflammation of the eye, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Some side effects of FML® eye drops are:

- fungal, bacterial or viral eye infections which may take longer to heal.
- blurred vision (cataract)
- in long term use, development of increased pressure in the eye.
- thinning of the cornea or sclera
- blurring of vision
- swelling of the eye or surrounding areas
- itching, redness, pain
- redness; inflammation of the cornea
- feeling of having something in the eye
- dilation of the pupil
- altered sense of taste

- visual disturbance or decreased sharpness of vision
- hypersensitivity
- rash
- discharge from the eye
- delayed wound healing
- droopy eyelids
- calcium deposits in the cornea

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects and they worry you.

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## **After using FML® eye drops**

### **Storage**

Keep your FML® eye drops in a cool place where the temperature stays below 30°C.

Store upright. Do not freeze the eye drops.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. Do not carry the eye drops in the pockets of your clothes.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not leave the top/lid off the bottle for any length of time to avoid contaminating the eye drops.

### **Disposal**

Write the date on the bottle when you open the eye drops and throw out any remaining solution after four weeks.

Eye drops contain a preservative which helps prevent germs growing in the solution for the first four weeks after opening the bottle.

After this time there is a greater risk that the drops may become contaminated and cause an eye infection. A new bottle should be opened.

If your doctor tells you to stop using the eye drops or they have passed their expiry date, ask your pharmacist what to do with any remaining solution.

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## **Product description**

### **What it looks like**

The eye drops come in a 5 mL sterile plastic bottle.

### **Ingredients**

Active ingredient:

Fluorometholone

Preservative:

Benzalkonium chloride

Inactive ingredients:

Polyvinyl alcohol, disodium edetate, sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate heptahydrate, polysorbate 80, sodium hydroxide and purified water.

### **Manufacturer/Supplier**

AbbVie Pty Ltd

241 O'Riordan Street

Mascot NSW 2020

AUSTRALIA

Ph: 1800 043 460

AbbVie Limited

6th Floor, 156-158 Victoria St

Wellington, 6011

NEW ZEALAND

PH: 0800 900 030

ARTG number:

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