

# FML®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using FML®?

FML® eye drops contain the active ingredient fluorometholone. FML® is used to treat inflammation (pain, swelling and redness) of the eye.

For more information, see Section [1. Why am I using FML®?](#) in the full CMI.

### 2. What should I know before I use FML®?

Check the list of ingredients at the end of the CMI. Do not use FML® if you have ever had an allergic reaction to any of them.

**Talk to your doctor before you use this medicine if he/she is not aware that you have any other medical conditions, use any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use FML®?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with FML® and affect how it works, or FML® may interfere with other medicines and affect how they work.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use FML®?

Your doctor will tell you the number of drops to use, when to use FML® and how long to use it.

More instructions can be found in Section [4. How do I use FML®?](#) in the full CMI.

### 5. What should I know while using FML®?

#### Things you should do

- Remind any doctor, dentist, pharmacist, or optometrist you visit that you are using FML®.
- Follow all your doctor's instructions carefully.
- Keep all your follow-up appointments so your

	condition can be closely checked.
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not stop using this medicine suddenly.</li> <li>• Do not touch the dropper tip against your eye, eye lid or any surface.</li> <li>• Do not use FML® while you are wearing soft contact lenses.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Wait for your vision to clear after using FML® before you drive or use machines.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• There is no information on the effects of taking FML® with alcohol.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Follow all instructions on the carton and bottle label.</li> <li>• Store it upright in a cool place, below 30°C away from heat, or sunlight. Do not freeze.</li> </ul>

For more information, see Section [5. What should I know while using FML®?](#) in the full CMI.

## 6. Are there any side effects?

Eye infection, increased pressure in the eye(s), blurred vision or other changes to your vision, eye redness, swelling of the eye, eye lid or surrounding areas, itchy eye(s), eye pain, irritation, dilation of the pupil, eye discharge, watery eye(s), calcium deposit in the cornea the feeling of having something in the eye, droopy eyelids, changes to taste, itchy, red skin rash, delayed wound healing, severe allergic reaction.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# FML®

**Active ingredient:** *fluorometholone* (floo-ro-meth-ol-lohn)

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using FML® eye drops. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using FML®.**

**Where to find information in this leaflet:**

- [1. Why am I using FML®?](#)
- [2. What should I know before I use FML®?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use FML®?](#)
- [5. What should I know while using FML®?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using FML®?

**FML® contains the active ingredient fluorometholone.**

**Fluorometholone acts by inhibiting the inflammation caused by certain irritations in the eye.**

**FML® is used to treat inflammation (pain, swelling and redness) of the eye .**

## **2. What should I know before I use FML®?**

### **Warnings**

#### **Do not use FML® if:**

- you have an eye infection caused by the Herpes simplex keratitis virus
- you have **any** infection in or around the eye
- you are allergic to fluorometholone, 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 has passed

#### **Check with your doctor if you:**

- have ever had an eye infection caused by the Herpes simplex virus
- have increased pressure in your eye (glaucoma)
- have had a recent eye infection
- have or have had any other eye conditions
- use any medicines for any other condition

- have had an allergy to any other medicines or any other substances, such as foods, preservatives or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

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.

## **Pregnancy and breastfeeding**

Make sure your doctor is aware that you are pregnant or plan to become pregnant. Safety of the use of topical steroids during pregnancy has not been established.

Make sure your doctor is aware that you are breastfeeding or intend to breastfeed. 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.

## **Use in children**

FML is not recommended for children younger than 2 years of age.

### **3. What if I am taking other medicines?**

Always tell your doctor or pharmacist about other medicines you are using. This includes prescription and non-prescription medicines, vitamins or supplements . There are no known interactions with FML® and other medicines. However, there's a small chance that taking certain CYP3A inhibitor medicines, like some antibiotics, antifungal, and antiretroviral drugs, could increase your risk of having side effects.

**Check with your optical practitioner, doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect FML®.**

### **4. How do I use FML®?**

#### **How much to use**

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.

#### **When to use FML®**

- Use FML® only as instructed by your doctor.
- Make sure you understand how frequently you should use it and when to start using it and when to finish using it.

In some instances, FML® needs to be used with other eye drops. Your doctor will let you know which drops, how to use them and how long to use them.

## **How to use FML®**

1. These eye drops are for topical use only.
2. Wash your hands well with soap and water.
3. If you wear soft contact lenses, remove them before using FML®.
4. Shake the bottle well.
5. Tear off the protective seal on any new bottle and throw the seal away. Remove the lid/cap.
6. Hold the bottle upside down in one hand between your thumb and index finger.
7. Using your other hand, gently pull down your lower eyelid to form a pouch or pocket.
8. Tilt your head back and look up. This might be easier if you are sitting or lying down.
9. Put the tip of the bottle close to your lower eyelid. Do not let the tip touch your eye, eyelid or any other surface.
10. Release one drop into the pouch or pocket formed between your eye and eyelid by gently squeezing the bottle.
11. If a drop misses your eye, try again, and wipe off any excess that runs down your cheek.
12. Close your eye. Do not blink or rub your eye.
13. 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.

14 Replace the lid/cap, sealing it tightly.

15 Wash your hands again with soap and water.

16 If you wear soft contact lenses, wait 15 minutes before replacing your soft contact lenses.

## **If you forget to use FML®**

It is important that you use FML® according to your doctor's instructions.

Use FML® 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 forget to use FML® and 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 number of drops to make up for the dose you missed.**

## **If you use too much FML®**

Immediately rinse your eyes with water.

**If FML® is accidentally swallowed, you should immediately:**

- phone the Poisons Information Centre **by calling 13 11 26** or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there appear to be no signs of discomfort or poisoning.**

## **5. What should I know while using FML®?**

### **Things you should do**

- If you wear soft contact lenses, remove them before using FML®, and wait at least 15 minutes before inserting them again. The preservative in FML® eye drops (benzalkonium chloride) may be absorbed and cause discolouration of soft contact lenses.
- Keep all your follow-up appointments with your doctor so your eye(s) can be checked.
- Use all the medication prescribed to treat your eye condition

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

### **Call your doctor straight away if:**

- you develop an eye infection, receive an eye injury, or have eye surgery
- you develop blurred vision or you notice any changes in your vision
- you become pregnant while using FML®
- your eye(s) seem(s) to be getting worse or is/are not improving.

### **Things you should not do**

- Do not touch the dropper tip against your eye, eyelid, or anything else, to avoid contaminating the eye drops.
- Do not stop using this medicine without checking with your doctor
- Do not give FML® to anyone else, even if they have the same condition as you.

### **Driving or using machines**

Wait for your vision to clear after using FML® before you drive or use machines.

## **Looking after your medicine**

Follow the instructions on the carton on how to take care of your medicine properly.

Store FML® UPRIGHT.

Store it in a cool place below 30°C away from heat or sunlight; for example:

- do not store it in the bathroom or near a sink, or
- do not store it in the car or on window sills

**Do not freeze the eye drops.**

**Keep it where young children cannot reach it.**

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

## **When to discard your medicine**

**Write the date on the bottle when you open the eye drops and discard unused contents 4 weeks after first opening it.**

## **Getting rid of any unwanted medicine**

If your doctor advises that you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not open a new bottle to use it if the expiry date has passed.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

FML® eye drops help most people with inflammation of the eye, but they may have unwanted side effects in a few people. The most common side effects are increased pressure in the eye, which is seen with long term use of FML® eye drops.

Although side effects that affect the whole body are rare, they can happen. At rare times, the body makes too much of a hormone called cortisol, which can cause weight gain, swelling in the face, and muscle weakness.

See the information below and, if you need to, ask your optical practitioner, doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Effects on the eye:</b></p> <ul style="list-style-type: none"><li>● swelling of the eye, eye lid or surrounding areas</li><li>● itchy eye</li><li>● eye redness</li><li>● eye pain</li><li>● eye irritation</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● the black circle in the center of the eye gets bigger</li> <li>● eye discharge</li> <li>● cloudy or white spot on the clear front part of the eye</li> <li>● the feeling of having something in the eye</li> <li>● droopy eyelids</li> <li>● watery eye(s)</li> </ul> <p><b>Effects on the body as a whole:</b></p> <ul style="list-style-type: none"> <li>● changes to taste</li> <li>● itchy, red skin rash</li> <li>● takes longer for a cut or injury to heal</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Effects on the eye:</b></p> <ul style="list-style-type: none"> <li>● increased pressure in the eye</li> <li>● eye infection</li> </ul>	<p><b>Call your doctor straight away, if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>blurred vision or other changes to your vision</li> </ul>	
<p><b>Effects on the body as a whole:</b></p> <ul style="list-style-type: none"> <li>severe allergic reaction, including swelling of the tongue, lips and throat, difficulty breathing.</li> </ul>	<p><b>Go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems) in Australia. By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop using any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What FML® contains

<b>Active ingredient (main ingredient)</b>	fluorometholone
<b>Preservative</b>	<ul style="list-style-type: none"><li>● benzalkonium chloride</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>● dibasic sodium phosphate heptahydrate</li><li>● disodium edetate</li><li>● monobasic sodium phosphate</li><li>● polysorbate 80</li><li>● polyvinyl alcohol</li><li>● purified water</li><li>● sodium chloride</li><li>● sodium hydroxide</li></ul>

**Do not use this medicine if you are allergic to any of these ingredients.**

## **What FML® looks like**

FML® is a milky suspension. It is supplied in a plastic dropper bottle containing 5 mL of liquid. (AUST R 23212).

## **Who distributes FML®?**

FML® is distributed in Australia by:

AbbVie Pty Ltd

Mascot NSW 2020

AUSTRALIA

Ph: 1800 252 224

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