

FLAREX™ Eye Drops 0.1%

Fluorometholone acetate

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you use FLAREX Eye Drops.

This leaflet answers some common questions about Flarex. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

You can also download the most up to date leaflet from www.novartis.com.au.

The updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you using FLAREX against the risks this medicine could have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What FLAREX is used for

FLAREX Eye Drops are used to treat the redness, swelling and other symptoms of eye inflammation.

FLAREX Eye Drops contain the active ingredient fluorometholone acetate. Fluorometholone belongs to a class of medicines known as "steroids" or "corticosteroids" which reduce inflammation.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

Use in children

This medicine is not recommended in children.

The safety and effectiveness of FLAREX Eye Drops has not been established in children.

Before you use FLAREX

When you must not use it

Do not use this medicine if you have an allergy to:

- Fluorometholone
- Any other similar medicines containing other types of "steroids"
- Any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not use FLAREX if:

- You are suffering from any type of viral infection of the eye
- You have tuberculosis of the eye
- You are suffering from any other types of infection including fungal or bacterial infections
- You have another infection that is not being treated
- You suffer from raised pressure within your eyes (intraocular pressure) or have been diagnosed with a condition known as "glaucoma".

Do not use this medicine if the expiry date has passed, the packaging is torn or the safety seal around the closure and neck area is broken.

If it has expired or is damaged, return it to your pharmacist for disposal.

Do not wear contact lenses while you are using FLAREX Eye Drops.

If you are not sure whether you should start to use FLAREX talk to your doctor.

Before you start to use it

Tell your doctor if:

- **You are pregnant or plan to become pregnant.**
FLAREX is not recommended in pregnant women or women of child bearing potential not using a contraceptive.
- You are breastfeeding.

Your doctor will discuss the possible risks and benefits of using FLAREX during breast-feeding.

If you have not told your doctor about any of the above, or any other general conditions, tell him or her before you start using this medicine.

Do not put FLAREX Eye Drops into your eye(s) while you are wearing contact lenses.

The preservative in FLAREX Eye Drops, benzalkonium chloride, may be deposited in contact lenses.

You can put your contact lenses back into your eyes 15 minutes after you have used FLAREX Eye Drops.

Taking or using other medicines

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

Some medicines and FLAREX Eye Drops may interfere with each other.

These include eye drops or eye ointments which contain non-steroidal anti-inflammatory drugs (NSAIDs).

Tell your doctor if you are using medicines containing ritonavir or cobicistat, as this may increase the amount of FLAREX in the blood.

Using FLAREX

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Use FLAREX Eye Drops only as prescribed by your doctor.

If you do not understand the instructions on the box ask your doctor or pharmacist for help.

How much to use

The usual dose of FLAREX Eye Drops is one to two drops in the affected eye, or eyes, two to four times a day.

The exact dose that your doctor prescribes for you will depend on the severity of your condition.

Do not use FLAREX Eye Drops more often than your doctor or pharmacist has told you.

Your pharmacist will put the dosing instructions on the bottle or carton of the drops.

It is important to follow your doctor's directions when using FLAREX Eye Drops.

How to use FLAREX

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

Follow these steps to use FLAREX Eye Drops:

1. Wash your hands thoroughly.
2. Shake the bottle well.
3. Remove the cap from the bottle.
4. Hold the bottle upside down in one hand between your thumb and middle finger (see Diagram 1).

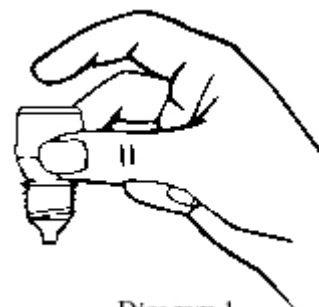


Diagram 1

5. While tilting your head back, gently pull the lower eyelid of your eye down using the forefinger of your other hand.
6. Place the dropper tip close to, but not touching, your lower eyelid and gently tap or press the base of the bottle with your forefinger to release one drop (see Diagrams 2 and 3).

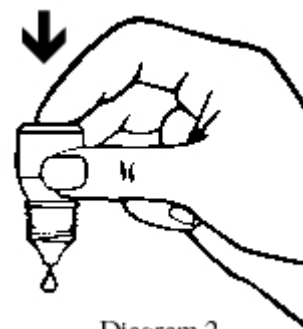


Diagram 2



Diagram 3

7. Close your eye gently without blinking.
8. If necessary, repeat the above steps 1-6 for your other eye.
9. Place the cap on the bottle and close it tightly.
10. Wash your hands again.

You may feel a slight burning sensation in the eye shortly after using FLAREX Eye Drops. If this persists, or is very uncomfortable, contact your doctor or pharmacist.

Do not touch the tip of the dropper to your eye or to any other surface.

This will help to prevent your eye drops becoming dirty or contaminated.

After using FLAREX Eye Drops, wait at least 5 minutes before putting any other eye drops in your eye(s).

Wait 15 minutes before replacing your contact lenses.

When to use it

Use FLAREX Eye Drops at the same time each day.

Using it at the same time each day will have the best effect. It will also help you remember when to use it.

How long to use it

Do not stop using FLAREX Eye Drops unless your doctor has advised you to.

If you are unsure about when to stop using FLAREX Eye Drops, you should talk to your doctor.

If you have been using FLAREX Eye Drops for more than a few days your doctor will slowly reduce the number of drops before you complete your treatment.

If you forget to use

If you forget to use FLAREX Eye Drops, you should put the drops that you missed in as soon as you remember and then go back to using them normally. If it is almost time for your next dose, skip the dose that you missed and take your next dose when you are due to.

Never use double the dose to make up for the one that you missed.

If you are not sure what to do, contact your doctor or pharmacist.

If you use too much (overdose)

If you accidentally put too many drops in your eye(s), immediately rinse your eye(s) with warm water.

If anyone accidentally swallows FLAREX Eye Drops, immediately telephone the nearest Poisons Information Centre on 13 11 26, or call your doctor, or go to Accident and Emergency at the nearest hospital.

While you are using FLAREX

Things you must do

If you become pregnant while using this medicine tell your doctor immediately.

If you are about to be started on any new medicine, remind your doctor or pharmacist that you are using FLAREX Eye Drops.

Tell any other doctor, dentist or pharmacist that you are using this medicine.

If you are going to have surgery tell your surgeon or anaesthetist that you are using FLAREX Eye Drops.

Tell your doctor if you experience swelling around the trunk and in the face area with weight gain.

This may occur when ophthalmic corticosteroids such as FLAREX eye drops become absorbed into your blood after intensive or long-term continuous treatment. These risks are especially important in predisposed patients, including children and patients treated with medicines containing ritonavir or cobicistat.

Things you must not do

Do not stop using FLAREX Eye Drops without first asking your doctor.

Do not use FLAREX Eye Drops to treat other complaints unless your doctor or pharmacist tells you to.

Do not give this medicine to anyone else, even if they appear to have the same condition as you.

Do not let children handle FLAREX Eye Drops.

If a child accidentally swallows any of the drops read the instructions under "If you use too much (overdose)".

Things to be careful of

Be careful of driving or operating machinery until you know how FLAREX Eye Drops affect you and your vision.

As with any eye medicines, temporary blurred vision or other visual disturbances may affect the ability to drive and use machinery in some people. If blurred vision occurs when you use your drops, wait until your vision is clear before driving.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using FLAREX Eye Drops.

This medicine helps most people but it may have some unwanted side effects in some 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.

Ask your doctor or pharmacist to answer any questions you may have.

Most side effects from FLAREX Eye Drops occur in, or around, the eye. These include:

- Blurred vision
- Eye pain, discomfort or irritation
- Eye redness
- A feeling that something is in the eye
- Increased pressure within the eye(s). If this continues, damage to the optic nerve and loss of vision may occur.

- An increased likelihood of experiencing eye infections
- A small puncture in the membranes surrounding the eye. This side effect is usually due to the presence of a viral infection in the eye which may weaken the membranes surrounding the eye.
- Increased tearing

Occasionally, some people notice unwanted effects in the rest of their body as a result of using FLAREX Eye Drops. These include:

- Change in taste sensation

Tell your doctor or pharmacist if you notice anything that is making you unwell.

Other side effects not listed above may also occur in some people.

After using FLAREX

Storage

Keep your eye drops in a cool, dry place where the temperature stays below 25°C. Do not refrigerate or freeze.

Put the top back on the bottle right away after use to avoid contaminating the eye drops. Do not leave the top off the bottle for any length of time.

Do not leave FLAREX Eye Drops in the car, in the bathroom or in other warm, damp places.

Heat and humidity 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.

Disposal

Throw out each bottle of FLAREX Eye Drops 4 weeks after opening.

Write the date on the bottle when you first open the drops to help you remember when to throw it out.

Product description

What it looks like

FLAREX Eye Drops are a sterile ophthalmic suspension that come in 5 mL or 10 mL dropper bottle.

Storage

Store below 25°C.

Shake well before use.

Ingredients

The active ingredient in FLAREX Eye Drops 0.1% is fluorometholone acetate (equivalent to 1 mg/mL fluorometholone).

FLAREX Eye Drops also contain:

- benzalkonium chloride 0.1 mg/mL as a preservative
- sodium biphosphate
- tyloxapol
- disodium edetate
- sodium chloride
- hyetellose
- hydrochloric acid/sodium hydroxide used to adjust pH
- purified water.

Supplier

This product is supplied in Australia by: Novartis Pharmaceuticals Australia Pty Limited

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