PART III: CONSUMER INFORMATION

Pr **FLAREX®**
Fluorometholone Acetate Ophthalmic Suspension

This leaflet is part III of a three-part "Product Monograph" published when FLAREX® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about FLAREX. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
FLAREX is used to treat eye allergies and eye inflammation.

What it does:
FLAREX contains a corticosteroid, fluorometholone acetate, that works by blocking the inflammatory response.

When it should not be used:
Do not use FLAREX if you:

- Are allergic (*hypersensitive*) to fluorometholone acetate or any of the other ingredients in FLAREX and its container (see What the important non-medicinal ingredients are).
- Are allergic to other corticosteroids.
- Have herpes simplex keratitis (inflamed cornea of the eye caused by the herpes simplex virus), smallpox, chickenpox, or any other viral infection of the eye.
- Have a mycobacterial infection of the eye, including tuberculosis.
- Have a fungal infection of the eye.
- Have an untreated bacterial eye infection.

What the medicinal ingredient is:
Fluorometholone acetate, 0.1% w/v

What the important nonmedicinal ingredients are:
Preservative: benzalkonium chloride
Others: edetate disodium, hydroxyethyl cellulose, monobasic sodium phosphate, sodium chloride, tyloxapol, sodium hydroxide and/or hydrochloric acid (to adjust pH), and purified water.

What dosage forms it comes in:
Eye drop suspension in 5 mL bottle

WARNINGS AND PRECAUTIONS

BEFORE you use FLAREX talk to your doctor or pharmacist if you:

- Have glaucoma (high pressure in the eyes) or family history of glaucoma. Your doctor needs to check the pressure in your eyes (*intraocular pressure*) regularly.
- Have diabetes. You may be at a higher risk of developing high pressure in the eyes or cataracts (clouding of the lens of the eye).
- Have a disease that causes thinning of the eye. Small tears (*perforations*) have occurred.
- Are taking a class of drugs known as nonsteroidal anti-inflammatory drugs (NSAIDs). Taking FLAREX with NSAIDs may slow healing of the eye.
- Have taken another corticosteroid drug before.
- Are over 65 years old.
- Are under 18 years old.

STOP taking FLAREX if you:

- Develop an allergic reaction.
- Develop an eye infection.

Talk to your doctor if your eye symptoms do not improve after 2 days of treatment with FLAREX. Do not take FLAREX for longer than 10 days unless your doctor tells you to. If you must take FLAREX past 10 days, it should be under your doctor's watch.

While taking FLAREX
If you use FLAREX* for a long time:

- Your doctor should check the pressure in your eyes regularly. This is especially important for individuals with glaucoma, a family history of glaucoma or diabetes. Taking FLAREX for an extended time increases the risk of developing increased pressure in the eyes, glaucoma, vision problems, and cataracts.

You may also be at risk for developing an eye infection.

Side effects of corticosteroids include swelling around the trunk and in the face area with weight gain. These may happen when a corticosteroid such as FLAREX is absorbed into your blood. Side effects may happen after intense or constant long-term treatment with FLAREX. The side effects may happen in predisposed patients such as children, and patients treated with medicines that contain ritonavir or cobicistat. Talk to your doctor if you experience swelling around the trunk and in the face area with weight gain.

Contact lenses
You should not wear contact lenses when you have eye inflammation.

If you must wear contact lenses, do not wear them while using FLAREX. FLAREX contains a preservative (*benzalkonium chloride*), which is known to discolour soft contact lenses. Avoid contact with soft contact lenses.

Remove your contact lenses before applying FLAREX and wait at least 15 minutes before putting your lenses back in.

Driving and using machinery
Your vision may become temporarily blurry after using FLAREX. If this occurs, wait until your vision clears before driving or using machinery.

Pregnancy and Breastfeeding
If you are pregnant, may be pregnant or planning to become pregnant, talk to your doctor or pharmacist before using FLAREX.

It is not known whether FLAREX is present in breastmilk. Talk to your doctor or pharmacist if you are breastfeeding or planning to breast-feed.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist about all the medicines you are taking, recently took or are planning to take, including those without a prescription.

Taking FLAREX at the same time as an NSAID may slow healing of the eye.

Tell your doctor if you are using medicines that contain ritonavir or cobicistat. This may increase the amount of fluorometholone in the blood.

PROPER USE OF THIS MEDICATION

SHAKE WELL BEFORE USE.

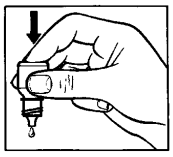
After removing the cap: if the security snap collar is loose, remove the snap collar before using FLAREX.

Usual adult dose:
1 to 2 drops in the affected eye(s) 2 to 4 times a day.

During the first 24 to 48 hours (1 to 2 days), you may apply as much as 2 drops every 2 hours.

How to use:

1



2

1. Get the FLAREX bottle and a mirror.
2. Shake well before use.
3. Hold the bottle, pointing down, between your thumb and fingers.
4. Tilt your head back.
5. Pull down your lower eyelid with a clean finger until there is a 'v' pocket between your eyelid and your eye. The drop will go in here (picture 1).
6. Bring the bottle tip close to the eye. Do this in front of a mirror if it helps.
7. Do not touch your eye, eyelid, surrounding areas or other surfaces with the dropper to avoid contaminating the suspension.
8. Gently press on the base of the bottle to release one drop at a time. Do not squeeze the bottle. It is designed so that a gentle press on the bottle is all that it needs (picture 2).
9. If you miss, try again.
10. If you apply FLAREX to both eyes, repeat the steps for your other eye.
11. Close the bottle immediately after use.

If you are using other eye drop or eye ointment medicines, leave at least 5 minutes between each medicine. Eye ointments should be used last.

Overdose:
If you use more FLAREX than you should, rinse it out with lukewarm water. Do not apply more FLAREX until it is time for your next regular dose.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:
If you forget to apply a dose of FLAREX, apply it as soon as you remember. However, if it is close to your next regular dose, skip the missed dose and continue with your usual schedule. **Do not** double dose to make up for a skipped dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, FLAREX may cause side effects, although not everybody gets them.

Side effects that may occur include: increased pressure in the eyes (*intraocular pressure*), eye pain, eye irritation, eye discomfort, such as burning or stinging, foreign sensation in the eye, blurred vision, eye redness, increased tearing, and bad taste in the mouth.

This is not a complete list of side effects. For any unexpected effects while taking FLAREX, contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature in an upright position. Protect from heat and freezing. Keep out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789, or**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 1908C
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
www.novartis.ca
or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at:
1-800-363-8883

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

Last revised: August 2, 2018
FLAREX is a registered trademark.