PART III: CONSUMER INFORMATION

Pr TRIESENCE®
triamcinolone acetonide injectable suspension
Mfr. Std.

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

ABOUT THIS MEDICATION

What the medication is used for:
TRIESENCE is a medicine that is used by your doctor during eye surgery.

What it does:
TRIESENCE is a suspension containing tiny white particles. The particles help to make the structures in your eye more clearly visible during surgery. The medicine itself is not being used to treat a condition**.**

When it should not be used:
- If you are allergic to triamcinolone or any other ingredients in TRIESENCE. For a full list of ingredients please see What the important nonmedicinal ingredients are.
- If you currently have an eye infection (see your doctor).
- If you currently have a systemic (throughout the body) fungal infection.

What the medicinal ingredient is:
The active ingredient is triamcinolone acetonide. One vial (1 mL) of TRIESENCE contains 40 mg of triamcinolone acetonide.

What the important nonmedicinal ingredients are:
Calcium chloride (dihydrate), carmellose sodium, magnesium chloride (hexahydrate), polysorbate 80, potassium chloride, sodium acetate (trihydrate), sodium citrate, sodium chloride and water for injection. Tiny amounts of sodium hydroxide and/or hydrochloric acid may be added to adjust acidity (pH) levels.

What dosage forms it comes in:
TRIESENCE is a milky white suspension (when shaken). It is available in a pack containing 1 vial of 1 mL of 4% (40 mg/mL) suspension.

LATEX-FREE STOPPER: Stopper is free from natural rubber or natural rubber latex.

WARNINGS AND PRECAUTIONS

BEFORE you are given TRIESENCE talk to your doctor if you:
- have ever had a reaction to triamcinolone or to any of the other ingredients in TRIESENCE**.**
- have, or have recently had, an eye infection.
- have been diagnosed with an active herpes simplex infection in your eye.
- have an active fungal infection in your body.
- have diabetes. You may be at a higher risk of developing an increase in eye pressure and/or cataracts (clouding of the lens of the eye).
- are pregnant or might become pregnant. **TRIESENCE is not recommended in pregnancy.**
- are breastfeeding or planning to breastfeed.

After you have been given TRIESENCE, consult your doctor immediately if:
- you develop intense inflammation or infection in or around the eye, ocular discharge, severe vision loss, or severe eye pain/irritation.

Driving and Using Machines
Eye surgery can temporarily affect your vision and your ability to drive or use machines. Do not drive or use machinery until your vision has returned to normal.

INTERACTIONS WITH THIS MEDICATION

Specific interaction studies have not been conducted with TRIESENCE.

Tell your doctor about all medicines, including eye drops, that you are using or plan to use. Include medicines you bought without a prescription.

PROPER USE OF THIS MEDICATION

Usual adult dose:
TRIESENCE will be administered by your doctor. The usual dose is less than 1 mL of TRIESENCE (1 to 4 mg of triamcinolone acetonide). The medicine is given by injection inside your eye during surgery. Depending on your condition your doctor may modify the dose.

TRIESENCE is removed from your eye before the end of the surgical procedure.

Do not resume contact lens wear until advised to do so by your doctor.

Overdose:
No case of overdose has been reported. Because TRIESENCE is administered by your doctor during surgery, the risk of accidental overdose is very small.

If you suspect you have been given an overdose, contact your doctor, a hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

TRIESENCE is administered by your doctor during surgery; there is no risk of a missed dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, TRIESENCE can cause side effects, but not everybody gets them.

If you get a severe allergic reaction after you have been given TRIESENCE, contact your doctor immediately.

Uncommon (affect 1 to 10 people in 1000) side effects include increased pressure in the eye and injury to the back of the eye. Your doctor will check for these side effects when you go back for your follow-up visits after surgery.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor	
		Only if severe	In all cases
Uncommon	Increased pressure in eye		✓
	Injury to the back of the eye		✓
Not known	Inflammation or infection in the eye		✓
	Reduced vision	✓	

This is not a complete list of side effects. For any unexpected effects after being given TRIESENCE contact your doctor.

HOW TO STORE IT

Your doctor or nurse will store TRIESENCE **at** 4ºC – 25ºC.

REPORTING SUSPECTED SIDE EFFECTS

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.
3 ways to report:

- **Online at MedEffect;**
- **By calling 1-866-234-2345 (toll-free);**
- **By completing a Consumer Side Effect Reporting Form and sending it by:**
  - **Fax to 1-866-678-6789 (toll-free), or**
  - **Mail to: Canada Vigilance Program**
    Health Canada, Postal Locator 1908C
    Ottawa, ON
    K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

NOTE: Contact your health professional if you need information about how to manage your side effects. 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 on the Health Canada website or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at:
1-800-363-8883.

This leaflet was prepared by
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