

**CONSUMER INFORMATION**

**FLUORESCITE\***  
**Fluorescein injection, USP**

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about FLUORESCITE\*. Contact your doctor or pharmacist if you have any questions about the drug.

**ABOUT THIS MEDICATION**

**What the medication is used for:**

FLUORESCITE\* is a diagnostic aid used by your doctor as part of certain eye exams.

**What it does:**

FLUORESCITE\* contains fluorescein sodium, which acts by lighting up your eye (*fluorescence*) to allow your doctor to see the blood moving through the small blood vessels at the back of your eye(s).

**When it should not be used:**

**FLUORESCITE\* should not be used if you are allergic to fluorescein sodium or any other of the ingredients in FLUORESCITE\* (see What the important nonmedicinal ingredients are).**

FLUORESCITE\* is injected into a vein and must not be injected into an artery or intrathecally (i.e. into any space surrounded by a sheath or membrane, such as the spine or brain).

**What the medicinal ingredient is:**

Fluorescein sodium (fluorescein 10 mg/mL)

**What the important nonmedicinal ingredients are:**

Hydrochloric acid and/or sodium hydroxide (to adjust pH), purified water

**What dosage forms it comes in:**

FLUORESCITE\* comes as a solution for intravenous injection in a 5 mL bottle.

**WARNINGS AND PRECAUTIONS**

**Serious Warnings and Precautions**

Your doctor must weigh the benefit of using FLUORESCITE\* as a diagnostic agent with the risk of a serious allergic reaction (see Side Effects and What to Do About Them).

**BEFORE FLUORESCITE\* is used, tell to your doctor if you:**

- Have ever had any side effects (other than nausea or vomiting) after FLUORESCITE\* was used.
- Have a history of allergies, including those to foods or other drugs.
- Have asthma.
- Have or have had heart disease.
- Have diabetes.

- Are taking many different drugs at the same type.
- Are pregnant or planning to become pregnant.

These are all important factors your doctor needs to know about when deciding whether to use FLUORESCITE\*.

**Low Salt Diet**

Before FLUORESCITE\* is used, tell your doctor if you are on a low salt diet. FLUORESCITE\* can contain a lot of salt.

**Breastfeeding**

Tell your doctor if you are or planning to breastfeed. Stop breastfeeding for at least 1 week after FLUORESCITE\* is used. Breast milk should be pumped and discarded.

**Driving and Using Machines**

If you experience blurry vision after FLUORESCITE\* is used, wait until your vision is back to normal before driving or using machines.

**INTERACTIONS WITH THIS MEDICATION**

Tell your doctor about all the medicines you are taking, recently took or are planning to take.

Drugs that may interact with FLUORESCITE\* include:

- Beta-blocking agents (e.g. propranolol, atenolol, sotalol).
- Antiarrhythmics (for irregular heartbeat, e.g. quinidine, digoxin).
- Probenecid (gout medicine).

If you are scheduled for any laboratory tests, tell your doctor that you were given FLUORESCITE\* as it may affect your test results.

**PROPER USE OF THIS MEDICATION**

**Usual dose:**

Your doctor will decide how much to give to you or your child and will administer FLUORESCITE\* by injection into a vein.

**Overdose:**

Your doctor should carefully decide how much FLUORESCITE\* to give you to avoid an overdose.

If you feel you have been given too much FLUORESCITE\*, contact your attending health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like all medicines, FLUORESCITE\* may cause side effects, but not everyone gets them.

Side effects that can occur at the injection site may include: general pain and soreness or accidental leakage of FLUORESCITE\* into surrounding areas, which may cause intense pain, local reaction and other effects, such as a dull aching pain in the injected arm. If this occurs, contact your healthcare professional immediately for medical attention.

Your skin may also become yellowish in colour and your urine may become bright. These effects should go away on their own after a few days.

Other side effects include: stomach pain/discomfort, nausea, vomiting, feeling hot or cold, dizziness, bad taste in the mouth, fainting, a tingling or numb sensation, headache, tremors, cough, shortness of breath, sneezing, throat irritation, rash or itchy skin, excess sweating and low or high blood pressure.

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

Tell your doctor if you experience any of the following side effects:

- Allergic reaction (includes itching, hives, difficulty breathing, swelling in the throat, chest tightness and itching or tingling around the lips or tongue).
- Severe shock or fits (*convulsions*).
- Swelling in the vein.
- Irregular heartbeat or cardiac arrest (i.e. heart stops beating).

Your doctor will watch you closely for any signs of these serious side effects, for at least 30 minutes after treatment, and give you immediate medical treatment if you need it.

*This is not a complete list of side effects.*

**HOW TO STORE IT**

The healthcare professional will store FLUORESCITE\* between 2°C to 30°C.

**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:

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- \$ Report online at [www.healthcanada.gc.ca/medeffect](http://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 0701D  
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](http://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.*

You may also report any suspected side effects to Novartis Pharmaceuticals Inc. directly at: 1-800-363-8883.

**MORE INFORMATION**

This document plus the full product information, prepared for health professionals can be found at: [www.novartis.ca](http://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.

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