

FLUORESCITE™ 10%

fluorescein sodium

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before you are given Fluorescite Injection.

This leaflet answers some common questions about Fluorescite Injection. It does not contain all 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 risks of you using Fluorescite against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What Fluorescite is used for

Fluorescite Injection contains fluorescein sodium which possesses the property of "fluorescence".

Fluorescite Injection is a "diagnostic agent". Fluorescite allows your doctor to see the blood moving through the small blood vessels at the back of your eye(s). It assists your doctor in determining if areas of your eye(s) are damaged or unhealthy.

Use in children

The safety and effectiveness of Fluorescite Injection has not been established.

Before Fluorescite is used

When it must not be used

Fluorescite Injection should not be used if you have an allergy to:

- fluorescein sodium
- any of the ingredients listed at the end of this leaflet under "Product Description"
- any other similar medicines

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.

Fluorescite Injection should not be used if:

- the vial/packaging shows signs of tampering
- the expiry date on the injection vial/carton has passed.

If this medicine is used after the expiry date has passed, it may not work as well.

If you are not sure whether Fluorescite Injection should be used in your case, talk to your doctor.

Before you are given it

Tell your doctor if you have had an allergy to any other medicines or any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- Heart disease
- Are on a controlled low sodium diet.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor can discuss with you the risks and benefits of using Fluorescite when you are pregnant.

Tell your doctor if you are breastfeeding or intend to breastfeed.

Fluorescite comes through breast milk for up to 7 days after it is used.

Discontinue breastfeeding for at least 7 days after Fluorescite use.

If you have not told your doctor about any of the above, tell them before they administer Fluorescite injection.

Taking or using other medicines

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

Some medicines and Fluorescite may interfere with each other. These include:

- Probenecid or other compounds that inhibit or compete with the active transport of organic anions
- beta-adrenergic blocking agents that are used to treat heart conditions, lower blood pressure and treat glaucoma.

Using Fluorescite when you are on a beta-adrenergic blocking medicine can cause a severe allergic reaction and affect the body's ability to respond to this reaction.

Your doctor or pharmacist have more information on medicines to be careful with or avoid when Fluorescite is to be used.

How Fluorescite is used

How much to use

The dose of Fluorescite Injection will be determined and administered by your doctor.

The usual adult dose of Fluorescite Injection is 10% or one 5 mL vial.

The usual dose for a child is based on the child's weight.

How it is used

Before using Fluorescite Injection your doctor will put some eye drops in your eye(s) that will open (dilate) your pupil(s). This allows your doctor to see the back of your eye(s) clearly.

Your doctor will usually administer Fluorescite Injection into your arm. It normally takes between 7 and 14 seconds for the fluorescein to reach the back of your eye(s).

Following the administration of Fluorescite Injection your doctor will turn the lights off and take a series of photographs of the back of your eye(s). These photographs will allow your doctor to study the movement of blood

through the vessels at the back of your eye(s).

If you use too much (overdose)

Your doctor will ensure that you are administered the correct dose of Fluorescite Injection.

After Fluorescite is used

Things to be aware of

It is likely that you will notice a yellow discolouration of your skin. Normally this will not last longer than 6 to 12 hours.

You will also notice a bright yellow colouring of your urine. Normally this will not last longer than 24 to 36 hours.

You may also notice a strong taste following the administration of Fluorescite Injection.

Fluorescite Injection can stain contact lenses.

Things to be careful of

You should not drive or operate any machinery after you have been given Fluorescite.

Temporary blurred vision or other visual disturbances may occur. Wait until your vision is clear before driving or operating machinery.

Side effects

Tell your doctor as soon as possible if you do not feel well following the use of Fluorescite Injection.

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.

Do not be alarmed by the following list of possible side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

Side effects that may occur at or near the site of the injection include:

- intense pain
- swelling
- a dull ache in your arm
- warm sensation
- feeling of weakness.

If you feel any pain or discomfort during the administration of Fluorescite Injection tell your doctor immediately.

Tell your doctor as soon as possible if you notice any of the following:

- strong taste in the mouth, metallic taste
- nausea and or headache
- gastrointestinal discomfort or vomiting
- abdominal pain
- dizziness, feeling light headed or fainting, which may be associated with low blood pressure or reduction in the flow of blood to the brain.
- low or high blood pressure
- pale appearance
- fatigue
- rash, itchy red skin
- muscle cramps
- tingling in fingers or toes
- tremor

- cough, throat irritation
- excessive sweating
- cold sweat
- skin discolouration.

These are serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- severe shock and or convulsions
- swelling in the vein used to administer the injection. This may be due to a clot in the vein.
- hypersensitivity or allergic type reactions

Some of the symptoms of an allergic reaction include:

- sneezing
 - itching, hives
 - difficulty breathing
 - swelling in the throat
 - tightness in the chest.
- These reactions may begin by an itching or tingling around the lips or tongue.
- cardiac arrest (the heart stops beating)
 - damage to the brain due to poor blood supply
 - irregular heartbeat.

These are very serious side effects. These side effects are very rare.

Tell your doctor immediately if you notice any discomfort in or around your chest or feel light headed shortly after the administration of Fluorescite Injection.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell after you are given Fluorescite Injection.

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

Product description

What it looks like

Fluorescite Injection 10% is a red-orange, sterile solution packed in a 5 mL glass vial with a stopper and aluminium flip-off cap. Fluorescite Injection 10% is for single dose use only. It contains no preservative and must be discarded after use. It has a pH of 8.0 to 9.8.

Ingredients

The active ingredient in Fluorescite Injection is fluorescein 100 mg in 1 mL (equivalent to 113.2 mg/mL of fluorescein sodium).

Fluorescite Injection also contains:

- sodium hydroxide and/or hydrochloric acid (to adjust pH)
- water for injections.

Storage

Store at or below 25°C. Do not freeze. Protect from light.

Supplier

Fluorescite 10% Injection is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited
 ABN 18 004 244 160
 54 Waterloo Road
 Macquarie Park NSW 2113

Telephone: 1-800-671-203.

Web site: www.novartis.com.au

Australian registration number

AUST R No: 124267.

Date of preparation

This leaflet was revised in August 2017.

© Novartis Pharmaceuticals Australia Pty Limited 2017

TM trademark of Novartis

Internal document code:

(flo260717c) based on PI (flo260717i)