

CONSUMER MEDICINE INFORMATION

What is in this Leaflet

This leaflet answers some common questions about FLUORESCITE[®] injection 10%. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of using FLUORESCITE[®] injection 10% against the expected benefits of using this medicine.

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 FLUORESCITE[®] injection is used for

FLUORESCITE[®] injection 10% contains fluorescein sodium. Fluorescein possesses the property of "fluorescence", which allows your doctor to see the blood moving through the small blood vessels at the back of your eye(s) and assists your doctor in determining if areas of your eye(s) are damaged or unhealthy.

As FLUORESCITE[®] injection 10% aids your doctor in making a diagnosis it is known as a "diagnostic agent".

Before using FLUORESCITE[®] injection

When it must not be used

FLUORESCITE[®] injection 10% should not be used if you have an allergy to:

- fluorescein sodium, or to any of the other ingredients in FLUORESCITE[®] injection 10% listed under *Product Description* at the end of this leaflet
- 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.

Ask your doctor or pharmacist to be sure you do not have any of these conditions.

FLUORESCITE[®] injection 10% should not be used if:

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

If you are not sure whether FLUORESCITE[®] injection 10% should be used in your case, talk to your doctor.

Before FLUORESCITE[®] injection 10% is used

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 medical conditions.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

This product comes through in breast milk for up to 4 days after using FLUORESCITE[®]. Breastfeeding should be discontinued for at least 4 days after use.

If you have not told your doctor about any of the above, tell them before administration of

FLUORESCITE[®] injection 10%.

Using other medicines

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

Some medicines and FLUORESCITE[®] injection 10% may interfere with each other. These include:

- compounds that inhibit or compete with the active transport of organic anions (eg. Probenecid)
- beta-adrenergic blocking agents (medication used to treat heart conditions such as high blood pressure and including eye drops (eg. Betoptic) used for glaucoma). They can reduce your body's response should you have an allergic reaction to this product.

These medicines may be affected by FLUORESCITE[®] injection 10%, or may affect how well it works.

Tell your doctor if you are on a controlled salt diet.

How to use FLUORESCITE[®] injection

How much to use

The dose of FLUORESCITE[®] injection 10% will be determined and administered by your doctor.

The usual adult dose of FLUORESCITE[®] injection 10% is 5 mL (one vial). The usual dose for a child is based on the child's weight.

How to use it

Before using FLUORESCITE[®] injection 10% 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 10% 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 10% 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 10%.

Side effects

Tell your doctor as soon as possible if you do not feel well following the use of FLUORESCITE[®] injection 10%.

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;
- a dull ache in your arm.

warm sensation **If you feel any pain or discomfort during the administration of FLUORESCITE[®] injection 10% tell your doctor immediately.**

Other side effects from use of FLUORESCITE[®] injection 10% can include:

- strong taste in the mouth; metallic taste
- nausea and / or headache;
- gastrointestinal discomfort / vomiting;

- dizziness, feeling light headed or fainting, which may be associated with a lowering of blood pressure or reduction in the flow of blood to the brain.
- fatigue
- rash
- tingling in fingers/toes
- tremor

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

Additional side effects that could be noticed include:

- severe shock and / or convulsions;
- swelling in the vein that has been used for the administration of FLUORESCITE[®] injection 10% due to clotting;
- hypersensitivity or allergic type reactions (e.g. itching, hives, difficulty breathing, swelling in the throat, a tightness in the chest). These reactions may initially be characterised by an itching or tingling around the lips or tongue;
- cardiac arrest (the heart stops beating);
- irregular heartbeat.

These are very serious side effects. You may need urgent medical attention or hospitalisation. 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 10%.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell after the administration of FLUORESCITE[®] injection 10%. Other side effects not listed above may also occur in some people.

After the use of FLUORESCITE[®] injection

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 10%.

Do not drive or operate any machinery if this procedure has affected your vision in any way.

Product description

What it looks like

FLUORESCITE[®] injection 10% comes in a 10% red-orange solution, packaged in a 5 mL glass vial with a

stopper and aluminium flip-off cap.

Ingredients

Active ingredients

- 100 mg/mL fluorescein (equivalent to 113.2mg / mL fluorescein sodium)

Other ingredients:

It 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:

Alcon Laboratories (Australia) Pty Ltd
Unit 10, 25 Frenchs Forest Road East
FRENCHS FOREST
NSW 2086

In New Zealand this product is distributed by:

Alcon New Zealand Limited
c/o Pharmaco (NZ) Limited
4 Fisher Crescent
Mt Wellington Auckland

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