PACKAGE LEAFLET: INFORMATION FOR THE USER

Fluorescein Sodium 100mg/ml Solution for Injection

Fluorescein sodium

INTRAVENOUS USE ONLY

The name of this medicine is Fluorescein Sodium 100mg/ml Solution for Injection, which will be referred to as Fluorescein Sodium Injection throughout this leaflet.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

IN THIS LEAFLET:

1. What Fluorescein Sodium Injection is and what it is used for

Fluorescein Sodium Injection contains the active ingredient fluorescein sodium which works as a diagnostic stain. It is used in a hospital-based procedure on the eye called fluorescein angiography of the ocular fundus (part of the eye). Fluorescein angiography is a test that allows the blood vessels in the back of the eye to be photographed as a fluorescent dye is injected into the bloodstream. This will assist your doctor in the diagnosis of diseases which affect these blood vessels, especially in elderly people and diabetics.

This medicinal product is for diagnostic use only.

2. What you need to know before you are given Fluorescein Sodium Injection

Do not use Fluorescein Sodium Injection if:

- you are allergic (hypersensitive) to fluorescein sodium or any of the other ingredients of this medicine (listed in section 6).

If the above applies to you or you are in any doubt you should ask your doctor or pharmacist for advice before being given this medicine.

Warning and Precautions:

Your doctor or other healthcare professional will give you this medicine through an injection into one of your veins. Fluorescein Sodium Injection is for intravenous injection only and MUST NOT be injected into the arteries (arterial route) or into the spinal column (intrathecal route).

You must tell your doctor if:

• You have previously undergone a hospital procedure on the eye called fluorescein angiography of the ocular fundus (a part of the eye)

• You have a history of allergy

• You have a history of heart or pulmonary disease

• You are taking drugs known as Beta-blockers including those applied in eye drops.

• You have kidney disease

Fluorescein sodium can induce serious allergic reactions that are more frequent in patients who have either experienced an adverse reaction to a previous administration of the medicine or in patients with a known history of allergy including food or drug-induced urticaria (red, itchy skin also known as hives), asthma, eczema and hayfever.

Your doctor will monitor you closely during and after the procedure and will ensure that appropriate emergency treatment facilities are available in case a serious reaction occurs.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription. Fluorescein sodium can sometimes interact with other medicines that you could be taking causing unwanted side effects. It is especially important to tell your doctor if you are taking any of the following:

- Medicines known as beta-blockers. These medicines can be used for a range of different therapeutic conditions and can be taken either by mouth or sometimes applied in eye drops. Common examples of beta-blockers include atenolol, bisoprolol, metoprolol and propranolol, betaxolol, levobunolol, and timolol.
- Medicines used for the treatment of gout (known as organic anion transporters) such as probenecid.

If you are due to have other diagnostic tests including blood, urine, and X-Ray investigations

Fluorescein Sodium Injection may interfere with the results of some blood and urine tests within 3 days of having the procedure. If you are having any blood or urine tests taken,you should tell the doctor or nurse that you have been given Fluorescein Sodium Injection.

If an X-ray procedure is conducted within 36 hours of injection, the resulting high visibility of some organs such as the kidneys may lead to misinterpretation of the results.

Pregnancy, breastfeeding and fertility

If you are pregnant or think you may be pregnant prior to using Fluorescein Sodium Injection, tell your doctor who will decide whether to give you this medicine or not.

As Fluorescein sodium is excreted in breast milk, stop all breast feeding for two days after administration of Fluorescein sodium.

Driving or operating machinery

The angiography procedure causes dilation of the pupil. Patients must abstain from driving a vehicle or operating machinery until the eyesight returns to normal.

Fluorescein Sodium Injection contains sodium

This medicinal product contains 2.54mmol (58.5mg) sodium per dose. This should be taken into consideration if you are on a controlled sodium diet.

3. How to use Fluorescein Sodium Injection

Adults (including the elderly)

A doctor will administer Fluorescein Sodium 100mg/ml Solution for Injection into the antecubital vein (the antecubital vein is situated in the arm) usually through a cannula. This medicine MUST NOT be injected via any other injection route, including into the arteries (arterial route) or into the spinal column (intrathecal route).

The exact dose, to be determined by the doctor, is up to a maximum dose of Fluorescein sodium 500mg (equivalent to one 5ml ampoule) administered by intravenous injection.

Children and adolescents

Fluorescein Sodium 100mg/ml Solution for Injection should not be used in people under the age of 18.

Use in patients with kidney problems

If you have a renal (kidney) impairment, the dose should not be adjusted.

If you are on kidney dialysis, your dose may be reduced to half of the normal recommended dose.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you have undergone a similar examination, please tell your doctor if you have experienced an intolerance reaction regardless of how severe it may or may not have been.

If you experience any of the following reactions during the examination immediately tell the doctor:

- swelling of the hands, face, lips or tongue.
- wheezing or difficulty in breathing.
- a sudden, unexpected rash or burning, red or peeling skin.
- severe dizziness or fainting.
- fast, deep breathing, cold clammy skin and feelings of anxiety.

If the product leaks into the tissue surrounding the site of the injection (extravasation), a painful inflammatory reaction could occur even leading to the death of tissue.

VERY COMMON May affect more than 1 in 10 people	- Nausea
COMMON May affect up to 1 in 10 people	- Vomiting - Blackout (also known as syncope) - Redness and itching of the skin - Discolouration (yellowing) of the skin and eyes - Discolouration (yellowing) of the urine - Abdominal discomfort -Pain at the site of injection (If the product leaks in surrounding the site of the injection (extravasatior inflammatory reaction could occur even leading to
UNCOMMON May affect up to 1 in 100 people	- Allergic reactions such as oedema of the face, urti also known as hives) - Feeling flushed - Abdominal pain - Feeling numb - Feeling dizzy - Headache - Tingling (also known as paresthesia) - Venous clot (also known as thrombophlebitis)
RARE May affect up to 1 in 1,000 people	- Lowering of blood pressure - Cardiac arrest - Chest pain - Breathing difficulties including shortness of breat - Severe allergic reaction (also known as an anaphy
VERY RARE May affect up to 1 in 10,000 people	- Fatal Anaphylactic (allergic) reaction - Myocardial infarction - Breathing difficulties - Collapse of the cardiovascular system - Convulsions (fits) - Laryngeal oedema - Pulmonary oedema - Angina pectoris

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme (Website: www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store your medicine

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and ampoule label after EXP. The expiry date refers to the last day of that month.

For single use only. Once opened the ampoule must be used immediately.

Any unused product or waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What Fluorescein Sodium Injection contains

The active substance is Fluorescein Sodium 100mg/ml (equivalent to 88.3mg/ml of anhydrous fluorescein).

The other ingredients are sodium hydroxide and water for injections.

What Fluorescein Sodium Injection looks like and the contents of the pack

Fluorescein Sodium Injection is a clear red solution supplied in 5ml colourless glass ampoules. Each pack contains 10 ampoules of solution.

Marketing Authorisation Holder:	The manufacturer of this product is:
SERB SA	**Serb S.A.S**
Avenue Louise, 480	Laboratoires Pharmaceutiques
1050 Brussels	40 avenue George V
, Belgium	75008 Paris – France
	If you have any medical inquiry,
	email: medinfo.uk1@serb.eu for help

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The following information is intended for healthcare professionals only:

Posology:

Use in adults, including the elderly:

One 5ml ampoule of fluorescein sodium 100mg/ml to be injected intravenously into the antecubital vein after taking precautions to avoid extravasation.

Use in paediatric patients:

Fluorescein Sodium Injection should not be used in patients below 18 years as efficacy and safety in this group has not been established.

Use in patients with renal insufficiency (glomerular filtration rate below 20ml/min):

There is limited data regarding the use of Fluorescein Sodium Injection in renally impaired patients (glomerular filtration rate below 20ml/min) and indicates, in general, no dose adjustment is required. Patients with renal impairment will exhibit a slower excretion rate (see section 5.2 of the SPC)

In dialysis patients:

Reduce the dose to 2.5ml (half an ampoule) as an intravenous injection.

Method of administration and fluorescence angiography:

- Fluorescein Sodium Injection should be used exclusively by qualified physicians with technical expertise in performing and interpreting fluorescence angiography.
- This product should only be administered intravenously.
- Flush intravenous cannulas with sterile sodium chloride solution (0.9%) before and after medicinal products are injected to avoid physical incompatibility reactions. The injection should be administered into the antecubital vein, after taking precautions to avoid extravasation using a 23 gauge butterfly needle for injection. Luminescence usually appears in the retina and choroidal vessels in 8 to 20 seconds.

Precaution and advice for administration:

Fluorescein Sodium Injection MUST NOT be injected outside of the vein due to the alkaline pH of the solution.

It is important that the needle is inserted properly into the vein before starting the injection of Fluorescein Sodium Injection

If the product leaks into the tissue surrounding the site of injection, further injection of fluorescein must be stopped **immediately.**

Incompatibilities:

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

To avoid physical incompatibilities, Fluorescein Sodium Injection should not be administered simultaneously with other solutions for injection, especially those with an acid pH (especially antihistamines) by the same intravenous route.

Special precautions for disposal and other handling:

For single use only. Any unused product or waste material should be disposed of in accordance with local requirements. Do not use Fluorescein for Injection if the ampoule is cracked or damaged or if there is any visible particulate matter or discolouration. After drawing up the solution into a syringe, the solution should be inspected visually again for particulate matter prior to administration. The solution should only be used if the solution is clear and free from particles.

Instructions to open the ampoule:

Ampoules are equipped with the OPC (One Point Cut) opening system and must be opened following the below instructions:

- Hold bottom part of ampoule between thumb and index finger of one hand.
- Gently tab top part of ampoule with a finger of the other hand to get all liquid into bottom part.
- Put the other hand on top of ampoule positioning thumb above coloured point.
- Press with light, even pressure. The ampoule should break with a clean snap.
- Using too much force can cause the ampoule to shatter. If the ampoule shatters or if the opened ampoule contains visible glass particles after opening, discard it and use a new ampoule.

Special warning

Fluorescein Sodium injection can trigger severe allergic reactions (section 4.4 of the SPC)

If serious allergic reactions occur during the first angiography, any further requirement for a fluorescein angiography must be carefully considered: the value of the diagnosis must be weighed with the risk of severe hypersensitivity which development is sometimes fatal.