

## **Package leaflet: Information for the user**

### **Fluorescein 100 mg/ml Solution for injection** fluorescein (as sodium)

**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, please ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Fluorescein 100 mg/ml Solution for injection is and what it is used for
2. What you need to know before you are given Fluorescein 100 mg/ml Solution for injection
3. How Fluorescein 100 mg/ml Solution for injection is given
4. Possible side effects
5. How to store Fluorescein 100 mg/ml Solution for injection
6. Contents of the pack and other information
7. Information for the Health care professional

#### **1. What Fluorescein 100 mg/ml Solution for injection is and what it is used for**

Fluorescein 100 mg/ml Solution for injection is a dye solution that makes the blood vessels at the back of your eye visible during an eye examination (this procedure is known as fluorescein angiography). This medicine is for diagnostic use only. It is not used to treat any condition.

#### **2. What you need to know before you are given Fluorescein 100 mg/ml Solution for injection**

**You should NOT be given Fluorescein 100 mg/ml Solution for injection:**

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

Tell your doctor if you think you are allergic or hypersensitive to fluorescein or any other ingredients in Fluorescein 100 mg/ml Solution for injection.

#### **Warnings and precautions**

**Tell your doctor before you are given Fluorescein 100 mg/ml Solution for injection**

- **if you have pre-existing conditions such as cardiovascular disease or diabetes mellitus.**
- **if you have impaired kidney function.** Fluorescein angiography testing may weaken or damage kidney function which can be a risk for someone with severe renal disease. Please consult with your doctor to see if this test is safe for you. If necessary, your doctor will give a lower dose of Fluorescein 100 mg/ml solution for injection.

- **if you use medicines called beta blockers.** Beta blockers are used to treat high blood pressure and a number of heart conditions and are also used in eye drops for the treatment of glaucoma. An allergic reaction to Fluorescein 100 mg/ml Solution for injection can cause a sudden drop in blood pressure. This may be greater in patients taking beta blockers (such as atenolol, sotalol, propranolol, metoprolol, bisoprolol).
- **if you have had a reaction to fluorescein before.** You may need to be given another drug to prevent you feeling sick.
- **if you are on a low sodium diet.** Fluorescein 100 mg/ml Solution for injection contains 72.45mg sodium per 5ml unit, equivalent to 3.62% of the WHO recommended maximum daily intake of 2g sodium for an adult.

If any of the above applies to you, or if you are not sure, please tell your doctor before you are given Fluorescein 100 mg/ml Solution for injection.

### **Other medicines and Fluorescein 100 mg/ml Solution for injection**

Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This medicinal product must not be mixed with other medicinal products.

### **Pregnancy, breast-feeding and fertility**

#### Pregnancy and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

If you are pregnant, Fluorescein 100 mg/ml Solution for injection should only be used after your doctor has prescribed it. Due to limited experience, caution should be exercised when considering the use of Fluorescein 100 mg/ml Solution for injection during pregnancy.

#### Breast-feeding

Tell your doctor if you are breast-feeding. Fluorescein, the active substance in Fluorescein 100 mg/ml Solution for injection, passes into the mother's milk where it is slowly eliminated. Therefore, after using Fluorescein 100 mg/ml Solution for injection, you should not breast feed for 7 days. During this period, breast milk should be expressed and thrown away.

### **Driving and using machines**

As part of your eye examination, you may be given eye drops which increase the size of the pupil of your eye. This 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.

### **Important information about some of the ingredients of Fluorescein**

Fluorescein 100 mg/ml Solution for injection contains 72.45mg sodium (main component of cooking/table salt) in each 5ml. This is equivalent to 3.62% of the recommended maximum daily dietary intake of sodium for an adult.

### **3. How Fluorescein 100 mg/ml Solution for injection is given**

Fluorescein 100 mg/ml Solution for injection will be administered by your doctor. Depending on your condition your doctor may modify the dose. However, since this product has not been studied in children, dose-adaptation data for children are not available.

Therefore, Fluorescein 100 mg/ml Solution for injection should not be used in patients below 18 years as efficacy and safety in this group have not been established.

#### **By injection:**

Usually one vial of Fluorescein 100 mg/ml Solution for injection which is given by injection into a vein in the arm. Fluorescein 100 mg/ml Solution for injection should not be injected intrathecally (into the spinal canal) or intra-arterially (into the arteries).

If you have any further questions about how Fluorescein 100 mg/ml Solution for injection is given, ask your doctor.

### **4. Possible side effects**

Like all medicines, Fluorescein 100 mg/ml Solution for injection can cause side effects, although not everybody gets them.

Fluorescein can have unexpectedly severe side effects. These are more likely if you have suffered a reaction to fluorescein before or if you suffer from allergies (food or drug allergies), eczema, asthma or hay fever.

Seek urgent medical advice if any of the following occurs after the use of Fluorescein 100 mg/ml solution:

Allergic reactions such as; swelling of the hands, face, lips or tongue, itching or tingling, hives, difficulty breathing, chest tightness. Dizziness or fainting, shock, convulsions, swelling in veins, irregular heartbeat, difficulty in breathing or swallowing, cardiac arrest.

The following side effects have been reported:

#### **Very common side effects**

*May affect more than 1 in 10 people*

Nausea

#### **Common side effects**

*May affect up to 1 in 10 people*

Vomiting, stomach problems, fainting, itching, escape of blood or fluid into the tissue,

#### **Uncommon side effects**

*May affect up to 1 in 100 people*

Headache, dizziness, sensation of pins and needles, cough, throat tightness, abdominal pain, hives, impaired speech, pain, feeling hot, hypersensitivity, inflammation of the veins

#### **Rare side effects**

*May affect up to 1 in 1,000 people*

Severe allergic reaction, cardiac arrest, low blood pressure, shock, difficulty in breathing or wheezing (bronchospasm).

### **Very rare side effects**

*May affect up to 1 in 10,000 people*

Anaphylactic shock, convulsion, angina pectoris, slow heart rate, fast heart rate, high blood pressure, cramp of blood vessels, cramp in the calf muscles, poor circulation, skin flushing, pallor, hot flush, stopping breathing, fluid on the lungs, asthma, decreased breathing function, swelling of the larynx, shortness of breath, swelling of the nose, sneezing.

### **Not Known**

*Frequency cannot be estimated from the available data*

Stroke, chest pain, loss of consciousness, shaking, abnormal or decreased skin sensation, rash, cold sweat, skin inflammation, sweating, oedema, generalised weakness, myocardial infarction, throat irritation, skin discolouration, abnormal sense of taste *and chills*.

After receiving Fluorescein 100 mg/ml Solution for injection, you may experience a change in the way things taste. Your skin may appear yellowish; this discoloration usually disappears after 6-12 hours. Your urine also may appear bright yellow; this may take 24-36 hours to return to normal.

After injection, inflammation of the vein and blood clots in the vein may occur. If during injection the solution leaks from the vein into the surrounding tissues, it can cause damage to the skin and inflammation of the veins, nerves and tissues close to the injection site; this can lead to severe pain. If you notice any pain or other problems at the injection site, tell your doctor; you may need to be given pain medication or other treatment to help with this.

If you experience any of the side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor.

### **Blood and urine tests**

It is possible that fluorescein may affect certain blood and urine tests for 3 to 4 days after you are given it. If you have any blood or urine tests or further X-rays during this period, tell your doctor that you have been given fluorescein.

### **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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. How to store Fluorescein 100 mg/ml Solution for injection**

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 label and outer carton (marked 'Exp'). The expiry date refers to the last day of that month.

Once open the vial must be used immediately.

Your doctor or nurse knows how to store Fluorescein 100 mg/ml Solution for injection.

This product does not require any special temperature storage conditions. Do not refrigerate or freeze. Keep the vial in the outer carton in order to protect from light.

Do not use Fluorescein 100 mg/ml Solution for Injection if the vial is cracked or damaged in any way.

The solution is to be inspected visually for particulate matter and discoloration prior to administration. The solution should only be used if the solution is clear and free from particles.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Fluorescein 100 mg/ml Solution for injection contains**

- The active substance is fluorescein.  
1 ml of solution contains 100 mg fluorescein (as 113.2 mg fluorescein sodium). One vial with 5 ml contains 500 mg fluorescein (as 566 mg fluorescein sodium).
- The other ingredients are sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment) and water for injections.

### **What Fluorescein 100 mg/ml Solution for injection looks like and contents of the pack**

Fluorescein 100 mg/ml Solution for injection is a clear red-orange solution for injection. Fluorescein 100 mg/ml Solution for injection is available in packages containing 1 vial or 12 vials containing 5 ml solution for injection.

### **Marketing Authorisation Holder**

Pharmargus Limited  
Pembroke House, 30 Pembroke Street Upper, Dublin 2, D02 EK84 Ireland

### **Manufacturer**

Eurofins Analytical Services Hungary Kft.  
Kerulet, Anonymus Utca 6/IV, IV Kerulet,  
Budapest, 1045, Hungary