

RETINOFLUOR™

Fluorescein Sodium Injection 10% and 25%

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Retinofluor. It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Retinofluor against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor.

Keep this leaflet in a safe place. You may need to read it again.

What Retinofluor is used for

Retinofluor is used to highlight blood vessels in the back of the eye so that a special camera can be used to take pictures and analyze the blood circulation in the eye. This helps doctors diagnose any problems or diseases of the eye.

This medicine belongs to a group of medicines called synthetic dyes. Retinofluor is an orange to red coloured fluorescent dye.

This medicine works by making the blood vessels in the eye fluoresce for a short time so that these vessels can be more easily seen in a photograph.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Before you are given Retinofluor

When you must not be given it

You should not be given Retinofluor if you have an allergy to:

- any medicine containing fluorescein sodium
- any of the ingredients listed at the end of this leaflet
- any other similar medicines such as synthetic dyes.

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.

You should not be given this medicine if you are pregnant.

It may affect your developing baby if you are given it during pregnancy.

Do not breast-feed if you are being given this medicine.

The active ingredient in Retinofluor passes into breast milk and there is a possibility that your baby may be affected.

This medicine should not be given to children.

Safety and effectiveness in children has not been established.

You should not be given this medicine if the solution is discoloured, cloudy, turbid, or a precipitate or particles are present.

The solution is normally an orange to red liquid.

The doctor or nurse will check to ensure the medicine is not past its expiry date and has not been tampered with.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- heart disease or heart problems
- diabetes mellitus
- asthma
- suffer from any allergies.

If you have not told your doctor about any of the above, tell him/her before you are given Retinofluor.

Taking other medicines

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

Some medicines and Retinofluor may interfere with each other.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being given this medicine.

How Retinofluor is given

Retinofluor must only be given by a doctor or nurse.

How it is given

Retinofluor is rapidly injected into a vein, usually at the bend of the elbow (the antecubital vein).

How much is given

Your doctor will decide what dose of Retinofluor you will receive. This depends on your medical condition and other factors, such as your weight.

Usually only a single dose of Retinofluor is required.

If you are given too much (overdose)

Retinofluor must only be given by a doctor or nurse so an overdose is not likely to occur.

If you experience any severe side effects tell your doctor or nurse immediately.

The symptoms of a side effect are listed under Side effects below.

If you notice any symptoms of an overdose immediately contact your doctor or go to the Emergency Department at the nearest hospital.

Contact the Poisons Information Centre on 13 11 26 for further advice on overdose management.

While you are being given Retinofluor

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you have been given Retinofluor.

Tell any other doctors, dentists, and pharmacists who treat you that you have been given this medicine.

If you are about to have any blood tests, tell your doctor that you have been given this medicine.

It may interfere with the results of some tests.

Things you must not do

Do not drive or operate machinery after being treated with Retinofluor.

This medicine causes a temporary decrease in vision in most people. Do not drive, operate machinery or do anything else that could be dangerous.

Things to be careful of

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Retinofluor.

This medicine may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

Ask your doctor to answer any questions you may have.

Retinofluor will cause:

- a temporary decrease in vision and images appear red as a result of the flash photography.
- urine to turn orange in colour for a brief period.

Tell your doctor or nurse if you notice any of the following and they worry you:

- nausea
- headache
- tingling or numbness in the hands or feet, tongue and lips
- excessive sneezing
- yellow discolouration of the skin and eyes.

The above list includes the more common side effects of your medicine.

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

- dizziness, light-headedness
- skin rash, itching, hives
- vomiting, stomach upset, pain or cramping
- intense lower back pain.

The above list includes serious side effects that may require medical attention.

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

- chest pain
- shortness of breath, difficulty breathing which may be very severe and usually worsens when lying down
- swelling, redness and severe pain at the injection site
- sudden severe signs of allergy including:
 - rash, itching or hives on the skin
 - swelling of face, lips or tongue
 - shortness of breath, wheezing or trouble breathing.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or nurse if you notice anything that is making you feel unwell.

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

After being given Retinofluor

Storage

Retinofluor will be stored in the surgery, pharmacy or ward of a hospital. The injection is kept in a cool, dry place protected from light and stored at less than 30°C.

Retinofluor will only be opened when it is time for you to have the injection.

Product description

What it looks like

Retinofluor is an orange to red solution in a clear glass vial sealed with a grey rubber stopper and aluminium seal and a plastic flip off top.

Ingredients

- Retinofluor 10% contains 100mg/mL of fluorescein sodium in water for injections.
- Retinofluor 25% contains 250mg/mL of fluorescein sodium in water for injections.
- Sodium hydroxide and/or hydrochloric acid are added to both strengths when required for pH adjustment.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes, alcohol or preservatives.

Manufacturer

Retinofluor is made in Australia by:
Phebra Pty Ltd
19 Orion Road
Lane Cove West, NSW 2066
Australia



- Retinofluor 10% 10mL vial.
AUST R 23130
Phebra product code INJ028
- Retinofluor 10% 5mL in a 7mL vial.
AUST R 121873
Phebra product code INJ140
- Retinofluor 25% 5mL in a 7mL vial.
AUST R 23138
Phebra product code INJ030

This leaflet was amended in May 2013.

Phebra and the Phi symbol are trademarks of Phebra Pty Ltd, 19 Orion Road, Lane Cove West, NSW 2066, Australia.