EN

PACKAGE LEAFLET: INFORMATION FOR THE USER

ANATERA™ 100 mg/ml solution for injection

Fluorescein

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 ANATERA™ 100 mg/ml solution for injection is and what it is used for

ANATERA™ 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 ANATERA™ 100 mg/ml solution for injection

You should <u>NOT</u> be given ANATERA™ 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 ANATERA™ 100 mg/ml solution for injection.

Warnings and precautions

Tell your doctor before you are given ANATERA™ 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 ANATERA™ 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 ANATERA™ 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.** ANATERA™ 100 mg/ml solution for injection contains up to 3.15 mmol (72.45 mg) sodium per dose.

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

Other medicines and ANATERA™ 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, ANATERA™ 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 ANATERA™ 100 mg/ ml solution for injection during pregnancy.

Breast feeding

Tell your doctor if you are breast feeding. Fluorescein, the active substance in ANATERA™ 100 mg/ml solution for injection, passes into the mother's milk where it is slowly eliminated. Therefore, after using ANATERA™ 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 ANATERA™ 100 mg/ml solution for injection

This medicinal product contains 72.45 mg sodium (main component of cooking/table salt) in each 5ml. This is equivalent to 3.7% of the recommended maximum daily dietary intake of sodium for an adult.

3. How ANATERA™ 100 mg/ml solution for injection is given

ANATERA™ 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, ANATERA™ 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 ANATERA™ 100 mg/ml solution for injection is given by injection into a vein in the arm. ANATERA™ 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 ANATERA™ 100 mg/ml solution for injection is given, ask your doctor.

4. Possible side effects

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

As listed previously, 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.

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 the national reporting system (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store ANATERA™ 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 opened the vial must be used immediately.
- Your doctor or nurse knows how to store ANATERA™ 100 mg/ml solution for injection:
- Do not store above 25°C. Do not freeze. Keep the vial in the outer carton in order to protect from light.
- Do not use ANATERA™ 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 ANATERA™ 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 and / or hydrochloric acid (used to adjust the pH of the solution) and water for injections.

What ANATERA™ 100 mg/ml solution for injection looks like and contents of the pack

ANATERA™ 100 mg/ml solution for injection is a clear red-orange solution for injection.

ANATERA™ 100 mg/ml solution for injection is available in packages containing 12 vials of 5 ml solution for injection.

Marketing Authorisation Holder
Alcon Eye Care UK Limited
Park View, Riverside Way
Watchmoor Park,
Camberley
Surrey, GU15 3YL
United Kingdom
PL 41809/0001

This product is also authorised in the EU under the following names:

Fluorescein ALCON™ 10% and FLUORESCITE™ 100 mg/ml solution for injection

Manufacturer:
Alcon Laboratories Belgium
Lichterveld 3
2870 Puurs-Sint-Amands
Belgium

This leaflet was last revised in 05/2021

7. Information for Health care professionals

The complete SmPC is provided as a separate document in the medicinal pack.

A1694074-0521