

PACKAGE LEAFLET: INFORMATION FOR THE USER

Verdye 5 mg/ml Injection
25 mg / 50 mg, powder for solution for injection
Indocyanine green

Read all of this leaflet carefully before you start using 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 or 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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Verdye is and what it is used for
2. What you need to know before you use Verdye
3. How to use Verdye
4. Possible side effects
5. How to store Verdye
6. Contents of the pack and other information

1. WHAT VERDYE IS AND WHAT IT IS USED FOR

What Verdye is

Verdye is a dark-green powder which is mixed with water for injections. The active substance in the solution is called indocyanine green, a coloured dye. This dye is then injected into one of your veins, where it mixes with your blood. The doctor will then be able to see:

- how far the dye moves from where it was injected;
- how much of it there is in various parts of your body.

What it is used for

It is used **for diagnosis only**, to find out which medical problems you may have, for example:

- a) how well the blood is flowing through a part of your body, through, for example:

- your heart
- your brain
- your liver
- a layer of the inner part of your eye called the choroid.

- b) how much blood there is in certain parts of your body.
- c) how well your liver is working.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE VERDYE

Do not use Verdye if

- you are allergic to indocyanine green, sodium iodide or iodine.
- you suffer from an over-active thyroid or from benign tumours of the thyroid.
- you have ever had any side effects after receiving these injections.

Special patient groups

Premature babies and new-born infants

If suffering from hyperbilirubinaemia, (an illness in which there is an unusually large amount of bilirubin in their blood), premature babies and new-born infants should not receive Verdye.

Warnings and precautions

Take special care with Verdye if

- you suffer from kidney failure. Consult your doctor to see whether this medicine is suitable for you.
- you need to have a test called “radio-active iodine uptake”, a test which assesses how well your thyroid gland functions. This test should be delayed for at least a week after you have received the Verdye, because the injection could affect the outcome of the thyroid test.

Other medicines and Verdye

Please note that the following information could also apply to products which you used some time ago or which you may be using in the future, so tell your doctor if

- you are taking any drugs that affect the way your liver works, because the process of eliminating indocyanine green from your body after the injection may be affected.
- you are taking, or think you may be taking, any of the drugs listed below, because some of these drugs could alter the way in which indocyanine green, the active substance in Verdye, is absorbed into the body, and could make the diagnosis inaccurate:
 - anticonvulsants (anti-epileptic drug)
 - cyclopropane (anaesthetic drug)
 - bisulphite compounds (preservative)
 - haloperidol (antipsychotic drug)
 - diamorphine (narcotic drug)
 - morphine (severe pain relieving drug)
 - nitrofurantoin (antibiotic)
 - opium alkaloids (anti-diarrhoea drugs)
 - phenobarbital (anti-epileptic and anaesthetic drug)

- pethidine (severe pain relieving drug)
- metamizole (pain relieving drug)
- methadone (drug for substitution treatment of opioid addicts)
- phenylbutazone (pain relieving drug)
- probenecid (drug for gout therapy)
- rifamycin (antibiotic)
- any injections containing sodium bisulphite (preservative).

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Tell your doctor before you receive Verdye if you are pregnant, think you may be pregnant or if you are breast-feeding. Your doctor will decide if it is appropriate to give you this medicine. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. Please check with your doctor before you consider driving or using machinery immediately after an injection.

3. HOW TO USE VERDYE

The injection is given only under the supervision of a doctor.

- Only water for injections is used to dissolve the indocyanine green.
- The solution for injection has to be inspected before it is given to you. If it is cloudy, it **will not** be used.
- The doctor or nurse injects the medicine directly into a vein using a needle, catheter or cardiac (heart) catheter.
- The vein chosen for the injection will depend on the kind of investigation you are having.
- If this medicine is injected into a vein in your arm, the doctor or nurse may first have to apply a temporary tourniquet. This is to make it easier to put the needle into the vein.
- The dose you receive will depend both on the sort of test which is being done and on your body weight.
- Your doctor may need to add something called **heparin** to the blood samples which she/he takes from you. (This is to prevent the samples from clotting).

Recommended dosages (mg/kg = milligrams of medicine for each kilogram you weigh)

Single doses

Adults (18–64 years), **the elderly** (65 years or more), **adolescents and children** (11–18 years):

- For investigating blood flow through the heart, brain, general blood circulation and micro-circulation, (for example, blood flows through parts of the eye, the choroid), the recommended dose is **0.1 – 0.3** mg/kg body weight.
- For assessing liver function, the recommended dose is **0.25 – 0.5** mg/kg body weight.

Maximum daily dose:**Adults and the elderly:**

The **total** daily dose should be kept below 5 mg/kg body weight.

Adolescents and Children:

- **(11–18 years)** the total daily dose should be kept below 5 mg/kg body weight
- **(2 – 11 years)** the total daily dose should be kept below 2.5 mg/kg body weight.
- **(0 month – 2 years)** the total daily dose should be kept below 1.25 mg/kg body weight

After the injection your doctor may measure how much dye there is in relation to the amount of blood. Measurements are usually taken at an artery, a finger or an earlobe.

You can ask your doctor to explain the techniques associated with your procedure.

If you use more of this medicine than you should

Please tell your doctor if you think you have been given too much of the medicine.

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

4. POSSIBLE SIDE EFFECTS

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

Severe allergic reaction: Very rare (affects fewer than one in every 10,000 patients):

The symptoms are:

- tightness in the throat
- itchy skin
- blotchy skin
- nettle-rash
- coronary artery spasm
- facial swelling (facial oedema)
- breathing difficulties
- tightness and/or pain in the chest
- faster heart beat
- a fall in blood pressure and shortness of breath
- heart failure (cardiac arrest)
- restlessness
- feeling sick (nausea)
- feeling of warmth
- flushes.

Together with the symptoms of the allergic reaction an increase of special white blood cells associated with allergic reactions can occur (hypereosinophilia).

The possibility of an allergic reaction is greater in patients with extremely serious kidney failure.

In the case of a **severe allergic reaction**, it may be necessary for you to receive **emergency treatment** such as:

- injections of adrenaline (epinephrine), hydrocortisone or antihistamine,
- artificial blood or electrolyte solutions (by drip feed),
- oxygen, to help your breathing.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system *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 Verdye

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

Do not store above 30°C.

Keep the glass vials in the outer carton in order to protect from light.

Once the solution for injection is prepared, it must be protected from light and used immediately.

Only use clear solutions free from visible particles.

Do not use Verdye after the expiry date which is stated on the carton and on the label of the vial. The expiry date refers to the last day of that month.

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 Verdye 5 mg/ml injection contains**

The active substance is indocyanine green.

Each amber glass vial contains:

either

25 mg indocyanine green as powder (to be reconstituted with 5 ml water for injections)

or

50 mg indocyanine green as powder (to be reconstituted with 10 ml water for injections).

What Verdye looks like and contents of the pack

Verdye powder for solution for injection is available in two package sizes: 5 vials containing either 25 mg or 50 mg of the active ingredient indocyanine green.

The container is sealed with a grey rubber stopper and fixed with an aluminium cap covered by a blue polypropylene cap.

Marketing Authorisation Holder and Manufacturer

Diagnostic Green GmbH

Otto-Hahn-Str. 20

85609 Aschheim-Dornach

Germany

Phone: +49 89 1241 477 20

Fax: +49 89 1241 477 29

E-mail: info@diagnosticgreen.com

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: VERDYE

Belgium: VERDYE 25 mg / VERDYE 50 mg

Italy: VERDYE

The Netherlands: VERDYE 25 mg / VERDYE 50 mg

Portugal: Verdye

Sweden: Verdye

United Kingdom: Verdye 5 mg/ml injection

This leaflet was last revised in 01/2016.

The SmPC is available on the MHRA website at the following:

<http://www.mhra.gov.uk/spc-pil/>