Package leaflet: Information for the user

Verdye 5 mg/ml 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

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 solution is **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.

When Verdye is **injected into the skin** or the subcutaneous fat tissue, it accumulates in lymph nodes and visualises lymphatic pathways.

What Verdye 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, 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.

Verdye is also used to make sentinel lymph nodes and lymphatic pathways visible or to identify them during surgery in adult breast cancer patients. For this purpose, the dye is injected into either the skin, the fat tissue under the skin, or the tumour area instead of into the veins.
The lymph nodes nearest the tumour are called sentinel lymph nodes. These lymph nodes and associated lymphatic vessels are most likely the first place to which cancer cells spread. When Verdye has reached the sentinel lymph nodes,

they can be checked to see if there are any cancer cells present. Verdye accumulates in the sentinel lymph nodes and can be detected by a special camera.

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
- if you suffer from an over-active thyroid or from benign tumours of the thyroid
- if you have ever had any side effects after receiving these injections
- in the following *Special patient groups*:
  Premature babies and new-born infants suffering from hyperbilirubinaemia (an illness in which there is an unusually large amount of bilirubin in their blood), must **not** receive Verdye.

Warnings and precautions
Talk to your doctor or pharmacist before using Verdye,
- if you suffer from kidney failure. Consult your doctor to see whether this medicine is suitable for you.
- if 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 Verdye, because the injection could affect the outcome of the thyroid test.
- because the skin may become more sensitive to sunlight and UV radiation in patients who receive Verdye injected into the skin or in the fat tissue under the skin. The patients concerned should therefore avoid direct sun exposure or artificial UV radiation (e.g. tanning booth) for at least 1 week after application of Verdye, or until any greenish discolouration at the injection site has disappeared.

Other medicines and Verdye
Tell your doctor or pharmacist if you are taking/using or have recently taken/used or might take/use any other medicines. This applies especially
- if you are taking any medicines that affect the way your liver works, because the process of eliminating indocyanine green from your body after the injection may be affected.
- if you are taking/using, or think you may be taking/using, any of the medicines listed below, because some of these 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 (medicines to treat epilepsy)
  - any injections containing sodium bisulphite (preservative)
  - bisulphite compounds (preservative)
  - cyclopropane (medicines used for anaesthesia)
  - heroine (medicine for substitution treatment of opioid addicts)
  - haloperidol (medicine to treat mental disorders)
  - metamizole (pain relieving medicine)
  - methadone (medicine for substitution treatment of opioid addicts)
  - morphine (severe pain-relieving medicine)
  - nitrofurantoin (medicine to treat bacterial infections)
  - opium alkaloids (medicines to treat diarrhoea)
  - pethidine (severe pain-relieving medicine)
  - phenobarbital (medicine to treat epilepsy and used for anaesthesia)
  - phenylbutazone (pain relieving medicine)
  - probenecid (medicine for gout therapy)
  - rifamycin (medicine to treat bacterial infections)

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you receive this medicine. Your doctor will decide if it is appropriate to give you this 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 powder.
- 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.
- If this medicine is injected into the skin, the fat tissue under the skin or the tumour area, a needle made for this purpose will be used.

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.
- For imaging of sentinel lymph nodes and visualisation of lymphatic pathways regardless of body weight:
  5 to 10 mg per injection. This corresponds to 1 to 2 ml of the reconstituted 5 mg/ml solution. The volume per injection should not exceed 2 ml. Larger volumes per injection can also be administered if higher dilutions are used.

- **Maximum daily dose** – for investigating blood flow and assessing liver function

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.

Use in children and adolescents
Single doses to be used in children and adolescents for investigating blood flow and assessing liver function are the same as for adults but the total daily dose should be kept below 2.5 mg/kg body weight in children 2 - 11 years and below 1.25 mg/kg body weight in children 0 - 2 years.

Use in patients with reduced kidney or liver function
Verdye should be dosed cautiously in the presence of severely reduced kidney or liver function.

Maximum daily dose - for imaging of sentinel lymph nodes and visualisation of lymphatic pathways

Adults and the elderly

For the detection of sentinel lymph nodes and visualisation of lymphatic pathways, the total daily dose should not exceed **10 mg**.

Use in children and adolescents
The use in children and adolescents for imaging of sentinel lymph nodes and visualisation of lymphatic pathways is not recommended due to insufficient data on safety and efficacy.

Measurements after injection
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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Severe allergic reaction: very rare (may affect up to 1 in 10 000 people)
The symptoms are:
- tightness in the throat
- itchy skin
- blotchy skin
- nettle-rash
- facial swelling (facial oedema)
- breathing difficulties
- tightness and/or pain in the chest
- faster heartbeat
- 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.

Other side effects
Furthermore, it has been reported that reversible greenish skin discolouration at the injection site can occur following application of indocyanine green into the skin or the subcutaneous fat tissue (frequency not known – cannot be estimated fom the available data).

Also, in very rare (may affect up to 1 in 10 000 people) cases nausea, urticaria or coronary artery spasm have been reported.

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: HPRA Pharmacovigilance, Website: www.hpra.ie.
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 sight and reach 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 this medicine 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 contains
The active substance is indocyanine green.

Each 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 is a dark-green powder for solution for injection in an amber glass vial, which is sealed with a grey rubber stopper and fixed with an aluminium cap covered by a blue polypropylene cap.

It is available in two pack sizes:
- 5 vials, each containing 25 mg of indocyanine green
- 5 vials, each containing 50 mg of indocyanine green

Not all pack sizes may be marketed.

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This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:
Austria, Belgium, Croatia, Czech Republic, Greece, Italy. Netherlands, Poland: VERDYE
Denmark, Finland, Hungary, Ireland, Portugal, Romania, Sweden, Slovenia, United Kingdom (Northern Ireland): Verdye

This leaflet was last revised in 06/2025.

The following information is intended for healthcare professionals only:

Handling instructions
This medicinal product should be reconstituted immediately prior to use.
This medicinal product is reconstituted by addition of 5 ml water for injections to the vial containing 25 mg of active substance or 10 ml water for injections to the vial containing 50 mg of active substance, respectively, giving in both cases a dark-green solution for injection with a concentration of 5 mg/ml (0.5 % w/v).

Visually inspect the reconstituted solution. If an incompatibility is noted in the form of unclear solution, the reconstituted solution should be discarded.
Only use clear solutions free from visible particles.

This medicinal product is for single use only.

The identification of sentinel lymph nodes and visualisation of lymphatic pathways may be impaired if they are located in deeper tissue layers or are covered by fatty tissue. Similarly, in patients with pronounced obesity (BMI >40), the mapping of sentinel lymph nodes and visualisation of lymphatic pathways may be impaired.