

Verdye Injection

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using Verdye Injection?

Verdye Injection contains the active ingredient indocyanine green. Verdye Injection is used for the diagnosis of eye, heart and liver conditions.

For more information, see Section [1. Why am I using Verdye Injection?](#) in the full CMI.

2. What should I know before I am given Verdye Injection?

Do not use if you have ever had an allergic reaction to indocyanine green.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given Verdye Injection?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Verdye Injection and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Verdye Injection?

- Your doctor will decide the correct dosage of Verdye Injection for you. This will depend on your age, weight and the investigation being performed.
- The doctor or nurse injects this medicine directly into a vein using a needle, catheter or cardiac (heart) catheter, depending on the kind of investigation you are having.

More instructions can be found in Section [4. How do I use Verdye Injection?](#) in the full CMI.

5. What should I know while being given Verdye Injection?

| | |
|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you have been given Verdye Injection.• Check with your doctor if you are pregnant or intend to become pregnant.• Talk to your doctor if you are breastfeeding or intend to breastfeed. |
| Things you should not do | <ul style="list-style-type: none">• Do not use Verdye Injection if you are allergic to indocyanine green, sodium iodide or iodine.• Do not use Verdye Injection if you suffer from an over-active thyroid or from benign tumours of the thyroid.• Do not use Verdye Injection if you have ever had any side effects after receiving these injections. |
| Driving or using machines | <ul style="list-style-type: none">• Check with your doctor before you consider driving or operating machinery immediately after an injection. |
| Looking after your medicine | <ul style="list-style-type: none">• Store below 25°C. Keep the glass vials in the outer carton in order to protect from light.• The vials will usually be stored in the clinic for you. |

For more information, see Section [5. What should I know while being given Verdye Injection?](#) in the full CMI.

6. Are there any side effects?

Symptoms of severe allergic reactions include: tightness in the throat, itchy skin, blotchy skin, nettle-rash, coronary artery spasm, facial swelling, 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, feeling of warmth or flushes.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Verdye Injection

Active ingredient(s): *indocyanine green*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Verdye Injection. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Verdye Injection.**

Where to find information in this leaflet:

1. [Why am I being given Verdye Injection?](#)
2. [What should I know before I am given Verdye Injection?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Verdye Injection?](#)
5. [What should I know while being given Verdye Injection?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I being given Verdye Injection?

Verdye Injection contains the active ingredient indocyanine green. Indocyanine green is a dark-green powder dye which is mixed with water for injections. 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

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

- how well the blood is flowing through a part of your body, for example:
 - o your heart,
 - o your brain,
 - o your liver,
 - o a layer of the inner part of your eye called the choroid.
- how much blood there is in certain parts of your body.
- how well your liver is working.

2. What should I know before I am given Verdye Injection?

Warnings

Do not use Verdye Injection 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.

Take special care with Verdye Injection 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 Verdye Injection, because the injection could affect the outcome of the thyroid test.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Your doctor will decide if it is appropriate to give you this medicine.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Ask your doctor or pharmacist for advice before taking any medicine.

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 Injection.

3. What if I am taking other medicines?

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

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 Injection, is absorbed into the body, and could make the diagnosis inaccurate:
 - o anticonvulsants (anti-epileptic drug)
 - o cyclopropane (anaesthetic drug)
 - o bisulphite compounds (preservative)

- o haloperidol (antipsychotic drug)
- o diamorphine (narcotic drug)
- o morphine (severe pain-relieving drug)
- o nitrofurantoin (antibiotic)
- o opium alkaloids (anti-diarrhoea drugs)
- o phenobarbital (anti-epileptic and anaesthetic drug)
- o pethidine (severe pain-relieving drug)
- o metamizole (pain relieving drug)
- o methadone (drug for substitution treatment of opioid addicts)
- o phenylbutazone (pain relieving drug)
- o probenecid (drug for gout therapy)
- o rifamycin (antibiotic)
- o any injections containing sodium bisulphite (preservative).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Verdyne Injection.

4. How do I use Verdyne Injection?

How Verdyne Injection is given

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).

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

If you use too much Verdyne Injection

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

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while being given Verdyne Injection?

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Verdyne Injection affects you.

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.

Looking after your medicine

Store below 25°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 Verdyne 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.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Verdye Injection vials will usually be stored in the clinic for you.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects are very rare and affect fewer than one in every 10,000 patients.

Serious side effects

| Serious side effects | What to do |
|--|--|
| <p>Severe allergic reaction:</p> <ul style="list-style-type: none">• 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 heartbeat• a fall in blood pressure and shortness of breath• heart failure (cardiac arrest)• death• restlessness• feeling sick (nausea)• feeling of warmth• flushes <p>Together with the symptoms of the allergic reaction an increase of special white blood cells associated with allergic reactions can occur (hypereosinophilia).</p> <p>The possibility of an allergic reaction is greater in patients with extremely serious kidney failure.</p> | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

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.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Verdye Injection contains

| | |
|--|-------------------|
| Active ingredient (main ingredient) | Indocyanine green |
| Other ingredients (inactive ingredients) | None |

Do not take this medicine if you are allergic to any of these ingredients.

What Verdye Injection looks like

Verdye powder for solution for injection is available in a 5 pack:

5 amber glass vials containing 25 mg of the active ingredient indocyanine green (AUST R 391356). The 25 mg vial is to be reconstituted with 5 mL water for injections.

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

Who distributes Verdye Injection

Clinect Pty Ltd

120-132 Atlantic Drive

Keysborough, VIC 3173

Australia

Telephone: 1800 899 005

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