

Package leaflet: Information for the user

**Zyogreen® 2.5 mg/mL,
solution for injection**

indocyanine green

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, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Zyogreen is and what it is used for
2. What you need to know before you are given Zyogreen
3. How Zyogreen is given
4. Possible side effects
5. How to store Zyogreen solution for injection
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1. What Zyogreen is and what it is used for

Pharmacotherapeutic class - ATC code: V04CX01

Zyogreen 2.5 mg/mL, solution for injection contains the active substance indocyanine green, which belongs to the class of diagnostic agents.

This medicine is for diagnostic use only. It is used for:

- Locating and visualising the sentinel node of lymphatic pathways (the first lymph node to which cancer spreads) during breast cancer surgery (use in oncology),
- Studying the vascularisation of the eye (choroidal vessels) using an examination known as infra-red ocular angiography (use in ophthalmology),
- Determining blood flow and functional reserve of the liver (use in hepatology),
- Measuring circulating blood volume and cardiac output.

2. What you need to know before you are given Zyogreen

Zyogreen must not be given

- if you are allergic to indocyanine green, sodium iodide or iodine or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from an over-active thyroid (when the thyroid gland makes too much thyroid hormone) or from benign tumours of the thyroid.
- if you have ever had any side effects after receiving these injections.

Warnings and precautions

Talk to your doctor or pharmacist before using Zyogreen. Your doctor will monitor you during and immediately after the injection of these products. The doctor will also ensure that the equipment needed for emergency care are available close at hand.

Tell your doctor:

- if you have a history of intolerance to Zyogreen.
- if you will perform or have performed thyroid test: The iodine content of Zyogreen can interfere with thyroid tests performed before or after administration of the dye. Therefore, radio-active iodine uptake studies should not be performed for at least a week following the use of this medicine.

Because the skin may become more sensitive to sunlight and UV radiation in patients who receive Zyogreen 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 Zyogreen, or until any greenish discolouration at the injection site has disappeared.

Allergic reactions

There is a risk of allergic reaction irrespective of the route of administration and the dose administered.

Serious allergic reactions (angioneurotic/Quincke's oedema or anaphylactic reaction) have been reported very rarely after administration of Zyogreen alone or after simultaneous administration of Zyogreen and fluorescein (another diagnostic dye product) at the same time.

Children

Zyogreen must not be used in premature infants or neonates with

hyperbilirubinemia (a disease in which an unusually large amount of bilirubin is present in their blood).

Other medicines and Zyogreen

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

The use of this medicine in ophthalmology can affect your vision temporarily and prevent you from driving vehicles or using machines.

Zyogreen contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially 'sodium-free'.

3. How Zyogreen is given

A healthcare professional will administer this medicine by injection under the skin (subcutaneous route) or into a vein (direct intravenous route).

Your doctor will determine the dose you will receive and will monitor the injection of this product.

The total dose injected should not exceed 0.5 mg/kg.

This medicine should never be diluted with solutions containing salts (such as physiological saline, Ringer's solutions), since these solutions cause precipitation of the dye.

Use in adults

• Locating the Sentinel node and lymphatic pathways (use in oncology):

The injection is made under the skin (subcutaneous route), close to the tumour or into the tumour.

The recommended dose is 5 to 10 mg (i.e. 2 to 4 mL of a 2.5 mg/mL solution). Simultaneous administration of indocyanine green with technetium (99m, Tc) may result in a decrease in its fluorescent properties.

• Use in ophthalmology:

The injection is given by direct intravenous route.

The recommended dose is 0.1 - 0.3 mg/kg body weight.

• Liver function diagnostics:

The injection is given by direct intravenous route.

The recommended dose is 0.25 - 0.5 mg/kg body weight.

• Measurement of circulating blood volume and cardiac output (use in cardiology):

The injection is given by direct intravenous route.

The recommended dose is 0.1 - 0.3 mg/kg body weight.

Use in children and adolescents

• Locating the Sentinel node and lymphatic pathways (use in oncology):

Since the safety and efficacy of Zyogreen in children and adolescents have not been established, its use in this population is not recommended.

• Use in ophthalmology:

The dose to be used depends on the weight of these patients, as in adults (see above, section 3 for adults).

• Liver function diagnostics:

The dose to be used depends on the weight of these patients, as in adults (see above, section 3 for adults).

• Measurement of circulating blood volume and cardiac output (use in cardiology):

The dose to be used depends on the weight of these patients, as in adults (see above, section 3 for adults).

If you are given more Zyogreen than you should

The doctor will take the necessary steps to avoid any problems.

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



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4. Possible side effects

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

The following side effects may occur:

- nausea, even vomiting,
- malaise (feeling of weakness, overall discomfort, illness, or simply not feeling well),
- hot flushes,
- excessive sweating (hypersudation),
- skin reactions (rash, urticaria or isolated itching),
- after administration of Zyogreen alone or after simultaneous administration of Zyogreen and fluorescein, severe allergic reactions:
 - Quincke's oedema (angioedema, sudden swelling of the face and neck with a burning sensation and difficulty in breathing),
 - anaphylactic shock (very severe life-threatening allergic reactions),
- allergic reactions,
- discolouration at the injection site,
- if the product is accidentally injected outside the vein, a temporary discolouration of the tissues is observed.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Provepharm at safety-uk@provepharm.com or via the Yellow Card Schema Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zyogreen

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 carton. The expiry date refers to the last day of that month.

Do not store above 30°C. Do not refrigerate or freeze. Store in the original package in order to protect from light.

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 Zyogreen contains

- The active substance is indocyanine green. Each mL of solution contains 2.5 mg indocyanine green. Each ampoule of 10 mL contains 25 mg indocyanine green.
- The other ingredients are: water for injection, sodium ascorbate.

What Zyogreen looks like and contents of the pack

This medicine is a deep emerald-green solution for injection packed in a brown glass ampoule. Each box contains a tray with 5 ampoules of 10 mL.

Marketing Authorisation Holder and Manufacturer

PROVEPHARM
22, Rue Marc Donadille
13013 Marseille
France

Manufacturer

CENEXI
52, Rue Marcel et Jacques Gaucher
94120 Fontenay-sous-Bois
France

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