Read all of this leaflet carefully before you start using this medicine because it contains important information about your treatment.

- Keep all medicines out of the reach of children.
- Store in a cool place.

What is this leaflet for?

1. What Indica carmine 40 mg/mL solution for injection is and what it is used for

Indica carmine 40 mg/mL solution for injection is used for the treatment of patients who are allergic to the active substance, Indica carmine. This medicine is used to treat certain skin diseases such as atopic dermatitis.

2. How to take Indica carmine 40 mg/mL solution for injection

- This medicine should be taken orally.
- This medicine should be taken once a day.
- Do not take this medicine with food.
- This medicine should be taken for at least 4 weeks.
- Store at a cool place.

3. Before you take Indica carmine 40 mg/mL solution for injection

- This medicine should be taken for a minimum of 4 weeks.
- Take this medicine at least 1 hour before meals.
- This medicine should be taken orally.
- This medicine should be taken once a day.
- Store at a cool place.

4. Possible side effects

- Tiredness
- Headache
- Nausea
- Diarrhoea
- Abdominal pain
- Vomiting
- Fever

5. How to store Indica carmine 40 mg/mL solution for injection

- Store at a cool place.
- Do not freeze.
- Do not use after the expiry date.
- Store in a cool place.

6. Contents of the pack and other information

- This medicinal product is available in the Member States of the EEA under the following names:
  - United Kingdom: Indica carmine 40 mg/mL solution for injection
  - Germany: Indica carmine 40 mg/mL solution for injection

For more information, please refer to the product’s packaging information. The current product information is available at www.medicines.org.uk.
THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS ONLY.

Considering the dark blue colour of Indigo carmine, a dilution is recommended during intravenous administration (for example a filter of 0.2 μm, with a filtering surface of at least 24 cm², composed of a hydrophilic polyvinyl chloride membrane).

Dosage

This medicinal product is to be injected by intravenous route. The initial recommended dosage is 1 ampoule of 5 ml, by slow intravenous injection.

A second ampoule may be injected 0 to 30 minutes after the first injection, if necessary.

In children:

The efficacy and safety of Indigo carmine in children has not been established.

In patients with renal insufficiency:

In patients with a clearance of creatinine ≥ 10 ml/min, Indigo carmine may be administered.

In patients with a clearance of creatinine < 10 ml/min, Indigo carmine should not be used.

In elderly:

No dosage adjustment is necessary.

In patients with low haemoglobin:

The excretion of Indigo carmine is mainly renal. Although there is no data in patients with hepatic failure, no dosage adjustment is required.

Storage:

Before opening the medicinal product does not require any special storage conditions. After opening the ampoule this medicine should be used immediately. The solution must only be used if the ampoule is not damaged, any unused solution should be thrown away.