

PACKAGE LEAFLET: INFORMATION FOR THE USER

Indigo carmine 40 mg/5 mL solution for injection

Indigotin (indigo carmine)

For Intravenous Injection Only

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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. WHAT Indigo carmine 40 mg/5 mL solution for injection IS AND WHAT IT IS USED FOR

Indigo carmine 40 mg/5 mL solution for injection contains the active substance indigotin (indigo carmine).

This medicine is for a diagnostic use only.

It is a dye used by the surgeon and anaesthetist during abdominal surgery.

The product discolours urine (to dark blue) within 5 to 15 minutes after injection.

This colour allows the identification of the ureter track (channels that evacuate urine from the kidneys to the bladder) and check that they have not been damaged during the surgery.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE Indigo carmine 40 mg/5 mL solution for injection

Do not use Indigo carmine 40 mg/5 mL solution for injection:

- If you are allergic to indigo carmine (the drug substance) or any other dye.

Warnings and precautions

Talk to your doctor or pharmacist before using Indigo carmine 40 mg/5 mL solution for injection:

- if you suffer from arterial hypertension (excessively high pressure of the blood in the arteries),
- if you suffer from heart failure (impairment of the heart functions) or angina pectoris (heart disease characterised by a sharp pain in the chest that can irradiate towards neighbouring regions),
- if you suffer from heart rhythm disorders (heart beats that are too fast, too slow or irregular) or cardiac conduction disorders,
- if you take medicines that slow your heart rhythm, affect your blood pressure or nitric oxide production (nitric oxide is a naturally occurring chemical in the body, which causes the muscles in the lining of the blood vessels to relax),

- if your blood pressure is instable,
- if you have a history of allergy,
- if you are pregnant,
- if you breast-feed.

You should observe a discolouration of urine after administration of this medicinal product.

Other medicines and Indigo carmine 40 mg/5 mL solution for injection:

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

Pregnancy, breast-feeding and fertility

As a precaution, it is preferable not to use this product during pregnancy or if you breast-feed.

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.

3. HOW TO USE Indigo carmine 40 mg/5 mL solution for injection

A healthcare professional will administer this medicine to you by slow injection into a vein.

Your doctor will determine the dose you will receive and will control the injection of this medicine. The dose usually injected is of 1 ampoule of 5 mL and may be repeated once if necessary.

If you were administered more Indigo carmine 40 mg/5 mL solution for injection than you should:

- your doctor will check your blood pressure and your heart rate,
- an overdose could induce a hypertensive crisis (sudden increase in blood pressure) and bradycardia (low heart rate).

A treatment with peripheral vasodilator may be considered (which will help lowering the blood pressure).

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:

- increase or decrease in blood pressure,
- slow down or acceleration of the pulse,
- cardiac conduction disorder,
- breath discomfort,
- rash or skin discolouration.

Reporting of side effects

If you get any side effect, tell your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report the side effects directly via the Yellow Card Scheme at: 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 Indigo carmine 40 mg/5 mL solution for injection

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 or ampoule after “EXP”.

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

Before opening: this medicinal product does not require any special storage conditions.

After opening the ampoule: this medicine must be used immediately.

Do not throw away any medicines via wastewater. 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 Indigo carmine 40 mg/5 mL solution for injection contains

- The active substance is indigotin (indigo carmine). Each ampoule of 5 mL contains 40 mg.
- The other ingredient is water for injections.

What Indigo carmine 40 mg/5 mL solution for injection looks like and content of the pack

This medicine is available as a solution for injection in ampoule. One box contains 10 ampoules.

Marketing Authorisation Holder

SERB S.A.

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Belgium
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Manufacturer

SERB

40 avenue George V
75008 Paris
France

Or

SERB S.A.

Avenue Louise 480
1050 Brussels
Belgium

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

United Kingdom	Indigo carmine 40 mg/5 mL, solution for injection
France	Carmyne 40 mg/5 mL, solution injectable
Germany	Indigokarmin Serb 40 mg/5 ml, Injektionslösung
Belgium	Carmin d'indigo Serb 40 mg/5 ml, solution injectable Indigokarmijn Serb 40 mg/5 ml, oplossing voor injectie Indigokarmin Serb 40 mg/5 ml, Injektionslösung
Luxemburg	Carmin d'indigo Serb 40 mg/5 ml, solution injectable
Netherlands	Indigokarmijn Serb 40 mg/5 ml oplossing voor injectie

This leaflet was last revised in March 2023.

The following information is intended for healthcare professionals only:

Considering the dark blue colour of Indigo carmine, a filtration is recommended during the intravenous administration (for example a filter of 0.45 µm, with a filtering surface of at least 2.8 cm², composed of a hydrophilic polyethersulfone 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 20 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 liver insufficiency:

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: this 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.