Package leaflet: Information for the user

Blumyne 40 mg/5 mL, solution for injection
Indigo carmine

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 Blumyne 40 mg/5 mL, solution for injection is and what it is used for

Pharmacotherapeutic group: diagnostic agents, ATC code: V04CH02

Blumyne contains the active substance indigo carmine (indigotin).

This medicine is for diagnostic use only.
It is a blue dye used by the surgeons and anesthetists during abdominal surgery. It discolours the urine (in dark blue) within 4 to 9 minutes after injection.
This colouration allows to identify the ureter tracks (channels that evacuate the urine from the kidney to the bladder) and check that they have not been damaged during the surgery.

2. What you need to know before you are given Blumyne 40 mg/5 mL, solution for injection

Blumyne 40 mg/5 mL, solution for injection must not be given
- if you are allergic to indigo carmine (indigotin) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given Blumyne
- If you take medicines that slow your heart rhythm
- If you suffer from heart rhythm disorders (heart beats that are too fast, too slow or irregular) or cardiac conduction disorders
- If you suffer from arterial hypertension (excessively high pressure of the blood in the arteries)
- If you suffer from heart failure (impairement of the heart functions) or angina pectoris (heart disease characterised by a sharp pain in the chest that can radiate towards neighbouring regions)
- If you have a history of allergy
- If you are pregnant
- If you are breast-feeding

You should observe a discolouration of the urine after administration of this medicine.

Children and adolescents

Not applicable.

Other medicines and Blumyne 40 mg/5 mL, solution for injection
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

Blumyne 40 mg/5 mL, solution for injection with food, drink and alcohol
Not applicable.

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, pharmacist or nurse for advice before having this medicine.

As a precaution, it is preferable not to use this medicine during pregnancy or if you are breast-feeding.

Driving and using machines
Not applicable.

3. How Blumyne 40 mg/5 mL, solution for injection is given

Considering the dark blue colour of Blumyne, filtration is recommended during intravenous administration (for example, a filter of 0.45 µm, with a filtering surface of at least 2.8 cm^2, composed of a hydrophilic polyethersulfone membrane).

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

The recommended dose 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.

If you are given more Blumyne 40 mg/5 mL, solution for injection than you should

Your doctor will monitor your blood pressure and heart rate.

An overdose could induce a hypertensive crisis (sudden increase in blood pressure) and bradycardia (low heart rate).

A treatment with peripheral vasodilatator 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, pharmacist or nurse.

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 heart rate,
- Cardiac conduction disorder,
- Breath discomfort,
- Rash or skin discolouration.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects via Provepharm at safety-uk@provepharm.com or directly 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 Blumyne 40 mg/5 mL, solution for injection

Keep this medicine out of the sight and reach of children.

You must not be given this medicine after the expiry date which is stated on the ampoule label and on the carton after EXP. The expiry date refers to the last day of that month.

Do not refrigerate or freeze.

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 Blumyne 40 mg/5 mL, solution for injection contains
- The active substance is indigo carmine (indigotin). Each mL of solution contains 8 mg of indigo carmine. Each ampoule of 5 mL contains 40 mg of indigo carmine.
- The other ingredients are: water for injections, citric acid monohydrate and/or sodium citrate (for pH adjustment).

What Blumyne 40 mg/5 mL, solution for injection looks like and contents of the pack
This medicine is a blue to bluish-purple solution for injection packed in brown glass ampoules. Each box contains a tray with 5 ampoules of 5 mL.

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13013 Marseille
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Manufacturer
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The following information is intended for healthcare professionals only:

Dosage
This medicine is intended to be injected intravenously. The initial recommended dose is 1 ampoule of 5 mL by slow IV injection.
A second ampoule may be injected 20 to 30 minutes after the first injection, if necessary.

Children
The efficacy and safety of Blumyne in children have not been established.

Patients with renal impairement

Blumyne may be administered in patients with a clearance of creatinine ≥ 10 mL/min.
Blumyne should not be used in patients with a clearance of creatinine < 10 mL/min.

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

Elderly
No dosage adjustment is necessary.

Storage

Do not refrigerate or freeze.
After opening the ampoule: this medicine should be used immediately.

Any unused product or waste material should be disposed of in accordance with local requirements.