Blumyne 40 mg/5 mL, solution for injection

Prescribing Information. Consult Summary of Product Characteristics before prescribing.
Marketing Authorisation number and basic NHS cost: PL 40051/0005. £96.02 per pack of 5, 5ml ampoules.

Legal Category: POM **Presentation:** Each 1ml of Solution for injection conatains 8mg of indigo carmine **Uses:** Blumyne is indicated for the intra-operative detection of suspected ureteral injuries during abdominal and pelvic surgery. **Dosage and Administration:** to be injected by intravenous route. The recommended initial 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. For diagnostic use only. **Method of Administartion:** Slow intravenous injection under monitoring of arterial pressure and heart rate during and a few minutes after the injection.

Paediatric population: The safety and efficacy in children has not been established. **Renal impairment***:* The excretion of indigo carmine is mainly renal. May be administered in patients with a clearance of creatinine ≥ 10 mL/min. Should not be used in patients with a clearance of creatinine < 10 mL/min. **Hepatic impairment:** There is no data in patients with hepatic impairment, however no dosage adjustment is necessary. **Elderly:** No adjustment is necessary. **Paediatric population:**The efficacy and safety in children has not been established. **Pregnancy:**There are no or limited amount of data from the use of indigo carmine in pregnant women. Blumyne is not recommended during pregnancy and in women of childbearing potential not using contraception. **Breast-feeding**
It is unknown whether indigo carmine or its metabolites are excreted in human milk. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to abstain from indigo carmine administration taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.
Special Warnings and Precautions For Use:
Considering the dark blue colour of Blumyne, filtration is recommended during intravenous administration. May cause a transient elevation of blood pressure and reflex bradycardia especially in patients under general anaesthesia or under spinal anaesthesia. Rare idiosyncratic reactions with bradycardia and hypotension have also been reported.
Intravenous injection should be stopped if the following symptoms occur: bradycardia, tachycardia, hypotension, hypertension, rash or erythema, respiratory symptoms such as dyspnea or bronchospasm. In patients with a creatinine clearance of < 10 mL/min, the time to onset of indigo carmine in urine may be delayed for several minutes. Therefore, it should not be used in patients with creatinine clearance of < 10 mL/min. Indigo carmine may interfere with pulse oxymetric methods. A discolouration of urine may be observed following administration of indigo carmine.
Should be used with caution in case of: concomitant use of medicines inducing bradycardia, heart rate and conduction disorders, high blood pressure, low heart rate, coronary disorders due to its peripheral vasoconstrictor effect.
Should be avoided in patients with: uncontrolled heart failure, history of allergic reactions, hemodynamic instability.
Contraindications: Hypersensitivity to the active substance or to any of the excipients
Side Effects: Consult the summary of product characteristics for other side effects.
The most common adverse reactions of indigo carmine are mainly related to its alpha-adrenergic activity and are of cardiovascular origin and include transient hypertension and bradycardia.
Serious adverse reactions of indigo carmine are very rare but include atrioventricular block and anaphylactoid reactions.
Further information is available from: Provepharm UK Ltd, 450 Bath Road, Heathrow, UB7 0EB
e-mail: safety-uk@provepharm.com **Tel:** +44 20 8078 5235
Prescribing Information drawn up August 2024

Adverse reactions should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse reactions should also be reported to safety-uk@provepharm.com