

Part VI: Summary of the risk management plan

Summary of risk management plan for: CARMYNE 40 mg/5 mL, solution injectable.

This is a summary of the risk management plan (RMP) for CARMYNE 40 mg/5 mL, solution injectable (hereafter referred as indigo carmine injection). The RMP details important risks of indigo carmine injection, how these risks can be minimised, and how more information will be obtained about the indigo carmine injection's risks and uncertainties (missing information).

Indigo carmine injection's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how indigo carmine injection should be used.

Important new concerns or changes to the current ones will be included in updates of indigo carmine injection's RMP.

I. The medicine and what it is used for

Indigo carmine is authorised for diagnostic use only and is indicated in intra-operative detection of ureteral injuries (see SmPC for the full indication). It contains indigo carmine as the active substance and it is given intravenously.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Indigo carmine injection, together with measures to minimise such risks are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of indigo carmine are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of indigo carmine. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

Important identified risks	<ul style="list-style-type: none">• Cardiovascular reactions due to alpha-adrenergic activity• Anaphylactoid reactions
Important potential risks	<ul style="list-style-type: none">• None
Missing information	<ul style="list-style-type: none">• None

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Indigo carmine.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for indigo carmine.