Summary of risk management plan for Benelyte solution for infusion

This is a summary of the risk management plan (RMP) for Benelyte solution for infusion. The RMP details important risks for use of Benelyte solution for infusion, how these risks can be minimised, and how more information will be obtained about Benelyte solution for infusion's risks and uncertainties (missing information).

Benelyte solution for infusion's reference safety information (summary of product characteristics (SmPC), package information leaflet (PIL)) includes essential information for healthcare professionals and patients on how Benelyte solution for infusion should be used.

Important new concerns or changes to the current ones will be included in updates of Benelyte solution for infusion's RMP.

I. The medicine and what it is used for

Benelyte solution for intravenous infusion is an electrolyte solution for paediatric patients that has been adjusted in its most important cation composition to the respective plasma concentration and is used for the correction of fluid and electrolyte disturbances.

Benelyte solution for infusion is indicated for paediatric patients such as neonates (0 to ≤28 days), infants (28 days to ≤2 years), children (2 to ≤12 years), and adolescents (12 to ≤14 years) as follows:

- Perioperative plasma-isotonic fluid and electrolyte replacement with partial coverage of carbohydrate requirements
- Short-term intravasal volume replacement
- Treatment of isotonic dehydration
- Use as carrier solution for compatible electrolyte concentrates and medicinal products.

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

Important risks of Benelyte solution for infusion, together with measures to minimise such risks and the proposed studies for learning more about Benelyte solution for infusion's 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 information leaflet 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 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*.

There is no need for additional risk minimization measures or additional pharmacovigilance activities

II.A List of important risks and missing information

Important risks of Benelyte solution for infusion are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 Benelyte solution for infusion. 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 longterm use of the medicine).

List of important risks and missing information	
Important identified risks	None
Important potential risk	None
Missing information	None

II.B Summary of important risks and missing information

Not applicable, as there is no important identified risk, important potential risk and missing information.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions to the marketing authorisations

There are no studies which are conditions of the marketing authorisation.

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

There are no studies required for Benelyte solution for infusion in the EEA.