EU Risk Management Plan for Tranexamic acid Kabi 10 mg/ml, solution for infusion

Part VI: Summary of the risk management plan

Summary of risk management plan for Tranexamic acid Kabi 10 mg/ml, solution for infusion (Tranexamic acid)

This is a summary of the risk management plan (RMP) for Tranexamic acid Kabi 10 mg/ml, solution for infusion. The RMP details important risks of Tranexamic acid Kabi 10 mg/ml, solution for infusion, how these risks can be minimised, and how more information will be obtained about Tranexamic acid Kabi 10 mg/ml, solution for infusion's risks and uncertainties (missing information).

Tranexamic acid Kabi 10 mg/ml, solution for infusion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Tranexamic acid Kabi 10 mg/ml, solution for infusion should be used.

Important new concerns or changes to the current ones will be included in updates of Tranexamic acid Kabi 10 mg/ml, solution for infusion's RMP.

I. The medicine and what it is used for

Tranexamic acid Kabi 10 mg/ml, solution for infusion is authorised in adults and children from one year for prevention and treatment of haemorrhages due to general or local fibrinolysis. Specific indications include:

- Haemorrhage caused by general or local fibrinolysis such as:
  - Menorrhagia and metrorrhagia
  - Gastrointestinal bleeding
  - Haemorrhagic urinary disorders, further to prostate surgery or surgical procedures affecting the urinary tract
- Ear Nose Throat surgery (adenoidectomy, tonsillectomy, dental extractions)
- Gynaecological surgery or disorders of obstetric origin
- Thoracic and abdominal surgery and other major surgical intervention such as cardiovascular surgery
- Management of haemorrhage due to the administration of a fibrinolytic agent.

It contains tranexamic acid as the active substance and is given by intravenous route. The administration is strictly limited to slow infusion of maximum 10 ml per minute.

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

Important risks of Tranexamic acid Kabi 10 mg/ml, solution for infusion, together with measures to minimise such risks and the proposed studies for learning more about Tranexamic acid Kabi 10 mg/ml, solution for infusion's risks, are outlined below.

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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 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 Tranexamic acid Kabi 10 mg/ml, 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 Tranexamic acid Kabi 10 mg/ml, 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 long-term use of the medicine);

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

II.B Summary of important risks

The safety information in the 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 Tranexamic acid Kabi 10 mg/ml, solution for infusion.

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

There are no studies required for Tranexamic acid Kabi 10 mg/ml, solution for infusion.