

PART VI SUMMARY OF RISK MANAGEMENT PLAN

Summary of risk management plan for Tranexamic acid Tillomed 100 mg/ml

Solution for Injection

This is a summary of the risk management plan (RMP) for Tranexamic acid Tillomed 100 mg/ml Solution for Injection. The RMP details important risks of Tranexamic acid Tillomed 100 mg/ml Solution for Injection, how these risks can be minimised, and how more information will be obtained about Tranexamic acid Tillomed 100 mg/ml Solution for Injection's risks and uncertainties (missing information).

Tranexamic acid Tillomed 100 mg/ml Solution for Injection's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how Tranexamic acid Tillomed 100 mg/ml Solution for Injection should be used.

Important new concerns or changes to the current ones will be included in updates of Tranexamic acid Tillomed 100 mg/ml Solution for Injection's RMP.

I. The medicine and what it is used for

Tranexamic acid Tillomed 100 mg/ml Solution for Injection is authorised for used in adults and children above one year of age for the prevention and treatment of bleeding due to a process that inhibits blood clotting called fibrinolysis. Specific indications include: heavy periods in women; gastrointestinal bleeding; haemorrhagic urinary disorders, further to prostate surgery or surgical procedures affecting the urinary tract; ear, nose or throat surgery; heart, abdominal or gynaecological surgery; bleeding after you have been treated with another medicine to break down blood clots. It contains Tranexamic acid as the active substance and it is given by slow intravenous injection.

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

Important risks of Tranexamic acid Tillomed 100 mg/ml Solution for Injection, together with measures to minimise such risks and the proposed studies for learning more about Tranexamic acid Tillomed 100 mg/ml Solution for Injection'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 PL and SmPC addressed to patients and health care 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 Tillomed 100 mg/ml Solution for Injection 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 Tillomed 100 mg/ml Solution for Injection. 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	<ul style="list-style-type: none"> • Thromboembolism
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 tranexamic acid Tillomed 100 mg/ml Solution for Injection.

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

There are no studies required for Tranexamic acid Tillomed 100 mg/ml Solution for Injection.