PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Tranexamic acid

This is a summary of the risk management plan (RMP) for Tranexamic acid. The RMP provides details on the important risks of Tranexamic acid, how these risks can be minimized, and how more information will be obtained about the risks and uncertainties (missing information) for Tranexamic acid. The summary of product characteristics (SmPC) and package leaflet (PL) for Tranexamic acid provide essential information to healthcare professionals and patients on how Tranexamic acid should be used.

Important new safety concerns and/or changes to the current safety concerns will be included in future updates of the RMP.

I. The medicine and what it is used for

Tranexamic acid is authorized for prevention and treatment of haemorrhages due to general or local fibrinolysis in adults and children from one year; refer to the SmPC for complete indication wording. It contains tranexamic acid as the active substance, and it is given by intravenous injection.

II. Risks associated with the medicine and activities to minimize or further characterize the risks

The important risks of Tranexamic acid, together with measures to minimize such risks and the proposed studies for learning more about Tranexamic acid's risks, are outlined below.

Measures to minimize 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 authorized pack size – the amount of medicine in a pack is chosen so as 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 minimize its risks.

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

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

II.A List of important risks and missing information

The important risks of Tranexamic acid are risks that need special risk management activities to further investigate or minimize 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. 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). The important risks and missing information for Tranexamic acid is listed in the table below.

Important identified risks	Thromboembolism
Important potential risks	None
Missing information	None

Important identified risk: Thromboembolism	
Evidence for linking the risk to the medicine	Evidence source: Medical literature.
Risk factors and risk groups	Patients with a history of thromboembolic diseases or in those with increased incidence of thromboembolic events in their family history (patients with a high risk of thrombophilia) are considered at risk of thromboembolic events. Moreover, major risk factors for thrombosis include age, exogenous factors such as surgery, hospitalization, immobility, trauma, pregnancy and the puerperium, hormone use, and endogenous factors such as comorbidities e.g. cancer, obesity, atrial fibrillation (major risk factor for stroke and systemic arterial thromboembolism), inherited and acquired hypercoagulation disorders. Disseminated intravascular coagulation is an example of serious pathologic overstimulation of the coagulation system, and as such tranexamic acid should not be used in patients with disseminated intravascular coagulation in most cases.
Risk minimization measures	**Routine risk minimization measures:** Discussed in SmPC section 4.3, 4.4, 4.5 and 4.8. Discussed in PL section 2 and 4. **Additional risk minimization measures:** None proposed

II.C Post-authorization development plan

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

There are no studies which are conditions of the marketing authorization or specific obligations of Tranexamic acid.

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

There are no studies required for Tranexamic acid.