Public Summary of the Risk Management Plan
Tranexamic acid Alternova 100 mg/ml, solution for injection
Alternova A/S
Date: 17-12-2014, version 1.5

VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

Tranexamic acid Alternova is used in adults and children over 1 year to prevent and treat bleeding due to fibrinolysis, which means that the blood has difficulty clotting.

VI.2.2 Summary of treatment benefits

Tranexamic acid belongs to a group of medicines called antifibrinolytics. Tranexamic acid is used to prevent excessive blood loss.

Antifibrinolytics work by preventing fibrinolysis, the natural process by which blood clots are broken down. They work by reducing the activity of an enzyme called plasmin that is responsible for breaking up the fibres in blood clots. In patients at risk of significant bleeding, antifibrinolytics ensure that blood clots are not broken down too rapidly, which helps to reduce blood loss.

Tranexamic acid is commonly used in the EU.

VI.2.3 Unknowns relating to treatment benefits

None

VI.2.4 Summary of safety concerns

Risk	**What is known**	**Preventability**
Thromboembolism	Patients with a current or a history of thromboembolic disease have an increased risk of experiencing serious adverse reactions when treated with tranexamic acid	Warning about the condition is given to doctors in the SPC section 4.3 Contraindications and 4.4 Special warnings and precautions for use and in to the patients in the PIL section 2.
Disseminated intravascular	Patients with disseminated	Warning about the condition is

Risk	What is known	Preventability
coagulation	intravascular coagulation (DIC) may be at increased risk for undesirable effects if treated with tranexamic acid.	given to doctors in the SPC section 4.3 Contraindications and 4.4 Special warnings and precautions for use and in to the patients in the PIL section 2.
Use in patients with renal impairment	Patients with renal impairment may experience accumulation of tranexamic acid and thus are at risk of experiencing overdose and undesirable effects.	Warning about the condition is given to doctors in the SPC section 4.3 Contraindications and 4.4 Special warnings and precautions for use and in to the patients in the PIL section 2.
Convulsions	Patients who receive high doses of tranexamic acid intravenously may experience convulsions. However, convulsions should not occur when tranexamic is given in the recommended lower doses.	Warning about the condition is given to doctors in the SPC section 4.3 Contraindications and 4.4 Special warnings and precautions for use and in to the patients in the PIL section 2.
Visual disturbances	Patients with pathological changes in the eyes should only be treated for longer periods with tranexamic acid after consultation with a specialist. In addition there is a risk for experiencing visual disturbances when treated with tranexamic acid and the patient should undergo regular examinations of the eyes.	Warning about the condition is given to doctors in the SPC section 4.4 Special warnings and precautions for use and in to the patients in the PIL section 2.
Urethral obstruction in patients with hematuria	Patients who experience haematuria during treatment with tranexamic acid is a risk of urethral obstruction which is serious as should be treated immediately.	Warning about the condition is given to doctors in the SPC section 4.4 Special warnings and precautions for use and in to the patients in the PIL section 2.
Intrethecal and intraventricular application, intracerebral application	Tranexamic acid should not be administered intrathecal, intraventricular or intracerebral due to risk of cerebral odema	Warning about the condition is given to doctors in the SPC section 4.4 Special warnings and precautions for use.

Risk	What is known	Preventability
	and convulsions.	
Interactions with other medical products.	Some medicinal products may interact with tranexamic aic and increase the risk of serious undisirable effects.	The medicinal products that may pose a risk is described in the SPC 4.5 Interaction with other medicinal products and other forms of interaction and to the patients in the PIL section 2.
Safety in pregnancy and lactation	Tranexamic acid is not recommended during the first trimester of pregnancy due to insufficient clinical data. Breast-feeding is not recommended when using tranexamic acid as the drug is excreted into human milk.	Recommendations for use of tranexamic acid are given to doctors in the SPC section 4.6 and to patients in the PIL section 2.

VI.2.5 Summary of additional risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

The Summary of Product Characteristics and the Package leaflet for Tranexamic acid Alternova can be found on the Finnish Medicines Agency after the product has been approved.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan (if applicable)

Not Applicable.

VI.2.7 Summary of changes to the risk management plan over time

Not Applicable.