VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

Tranexamic acid is used to control bleeding in a number of different conditions. It reduces unwanted or heavy bleeding following some surgery (such as surgery on the prostate, bladder, or cervix), nosebleeds, heavy periods (menorrhagia), bleeding inside the eye, tooth extractions in people who bleed more easily than normal, and in a condition called hereditary angio-oedema

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. The product has been used for several decades in patients undergoing certain dental or surgical operations as well as other patients at risk of complications from bleeding.

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
Excessive blod clotting or bleeding throughout the body (Disseminated Intravascular Coagulation (DIC))	Patients with the condition Disseminated Intravascular Coagulation (DIC) - a serious disorder in which the proteins that control blood clotting become over active which causes excessive clotting or bleeding throughout the body may be at increased risk for undesirable effects if 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.
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.
Blood clots (Thromboembolism)	Patients with a current or a history of blood clots 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.
Blood in the urine (Haematuria)	Patients who experience blood in the urine 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.
Convulsions	Patients who receive high doses of tranexamic acid intravenously may experience	Warning about the condition is given to doctors in the SPC section 4.3 Contraindications

Risk	What is known	Preventability
	convulsions. However, convulsions should not occure when tranexamic is given in the recommended lower doses.	and 4.4 Special warnings and precautions for use and in to the 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 Tranexamsyre Alternova can be found on the Danish Health and 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.

Table 1. Major changes to the Risk Management Plan over time

Version	Date	Safety Concerns	Comment
<number>	<At time of authorisation dd/mm/yyyy>	<Identified Risks Potential Risks Missing information>	
<E.g. 7.0>	<E.g. 17/08/2012>	<E.g. Allergic conditions added as an identified risk Hypersensitivity removed as an identified risk Severe infection added as an identified risk Convulsions added as a potential risk>	<E.g. The previous term hypersensitivity was updated to allergic conditions to include angioedema and urticarial>
etc.			