PUBLIC SUMMARY OF RISK MANAGEMENT PLAN (RMP)

TRANEXAMIC ACID ORION 100 MG/ML SOLUTION FOR INJECTION

ORION CORPORATION

DATE: 11-09-2014, VERSION 1

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Tranexamic acid is a medicine which is used in treating and preventing bleeding problems such as in menorrhagia (heavy periods), gastrointestinal bleeding or during certain surgery procedures. 10 to 20% of all menstruating women experience blood loss severe enough to be defined clinically as menorrhagia. The incidence of upper gastrointestinal bleeding in adults is estimated ranging from 40 to 150 cases per 100,000 population per year. Lower gastrointestinal bleeding has an estimated incidence of 20 to 30 cases per 100,000 population per year. Tranexamic acid is frequently used in surgeries with high risk of blood loss such as cardiac procedures.

VI.2.2 Summary of treatment benefits

Tranexamic acid is given to stop or reduce heavy bleeding. When bleeding, body forms clots to stop the bleeding. In some people these clots break down causing too much bleeding. Tranexamic acid works by stopping the clots from breaking down and so reduces the unwanted bleeding. Tranexamic acid is used to control bleeding in a number of different conditions. It reduces unwanted or heavy bleeding following certain surgery (such as cardiac procedures) and e.g. in heavy menstrual bleeding. Use of tranexamic acid in surgeries with high risk of blood loss reduces need for blood transfusions. Tranexamic acid also reduces the risk of complications (e.g. severe anaemia) related to menorrhagia and gastrointestinal bleeding.

VI.2.3 Unknowns relating to treatment benefits

There is insufficient clinical data on the use of tranexamic acid in pregnant women. In children, data on efficacy, posology and safety for approved indications are limited. The efficacy, posology and safety of tranexamic acid in children undergoing cardiac surgery have not been fully established. No specific dose-effect study or pharmacokinetic study has been conducted in children.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Convulsions	Cases of convulsions have been reported in association with tranexamic acid treatment. In most of these cases, high doses of tranexamic acid were used.	If patient has had convulsions, tranexamic acid should not be administered. Doctor must use the minimal dose possible to avoid convulsions following treatment with tranexamic acid.
Visual disturbances	Visual disturbances including impaired colour vision has been reported in association with tranexamic acid treatment.	If patient is on a long-term treatment with tranexamic acid, attention should be paid to possible disturbances of colour vision and if necessary the treatment should be discontinued. With continuous long-term use of tranexamic acid solution for injection, regular ophthalmologic examinations (eye examinations including visual acuity, colour vision, fundus, visual field etc.) are indicated. With pathological ophthalmic changes, particularly with diseases of the retina, doctor must take a decision after consulting a specialist on the necessity for the long-term use of tranexamic acid solution for injection in each case.
Thromboembolic events (risk of having blood clots)	Treatment with tranexamic acid increases the risk of having blood clots.	Tranexamic acid should not be used if patient currently has a disease leading to blood clots or if patient has a condition called 'consumption coagulopathy' where blood in the whole body starts to clot. Patients should specifically tell doctor if they take: - other medicines that help blood to clot called antifibrinolytic medicines - medicines that prevent blood clotting, called thrombolytic medicines

Risk	What is known	Preventability
		- oral contraceptives.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Use in patients with renal impairment (kidney problems)	Kidney problems may lead to a risk of accumulation (too high levels of tranexamic acid in the blood). Therefore tranexamic acid should not be used in patients with severe kidney problems. For patients with mild to moderate kidney problems, the dose of tranexamic acid will be reduced according to a test performed on blood (serum creatinine level).
Haematuria (blood in urine)	Blood in urine while using tranexamic acid may lead to urinary tract obstruction. Doctor must be informed if patient has had blood in urine.
Use in patients with disseminated intravascular coagulation (blood clotting problem)	If patient has blood clotting problem called disseminated intravascular coagulation, tranexamic acid may not be used, except if patient has acute severe bleeding and blood tests have shown the process that inhibits blood clotting called fibrinolysis is activated.

Missing information

Risk	What is known
Use during pregnancy	There is insufficient clinical data on the use of tranexamic acid in pregnant women. Tranexamic acid should be used throughout pregnancy only if the expected benefit justifies the potential risk.
Use in paediatric population	Data on efficacy, posology and safety for approved indications are limited. The efficacy, posology and safety of tranexamic acid in children undergoing cardiac surgery have not been fully established. No specific dose-effect study or pharmacokinetic study has been conducted in children.

VI.2.5 Summary of 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 this product can be found in the national authority's web page www.fimea.fi.

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.