Medicines & Healthcare products Regulatory Agency

MHRA

Public Assessment Report

National Procedure

Tranexamic Acid 500 mg Tablets

tranexamic acid

PL 14251/0300

MANX HEALTHCARE LIMITED

LAY SUMMARY

Tranexamic Acid 500 mg Tablets
tranexamic acid

This is a summary of the Public Assessment Report (PAR) for Tranexamic Acid 500 mg Tablets. It explains how this product was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use this product.

For practical information about using Tranexamic Acid 500 mg Tablets, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What are Tranexamic Acid 500 mg Tablets and what are they used for?
This application is the same as Tranexamic acid 500 mg Tablets, PL 14251/0026, which is already authorised.

The Company responsible for Tranexamic acid 500 mg Tablets has agreed that its scientific data can be used as the basis for the grant of an identical licence for Tranexamic Acid 500 mg Tablets.

Tranexamic acid 500 mg Tablets can be used to prevent or reduce bleeding for a short period of time in many different conditions. They can be used to reduce bleeding for the following reasons:

- following prostate surgery
- heavy periods
- nose bleeds
- following surgery to the cervix in women
- bleeding inside the eye
- tooth removal in haemophiliacs
- a hereditary disease called angioneurotic oedema (HANO)

How do Tranexamic Acid 500 mg Tablets work?
Tranexamic Acid is an antifibrinolytic agent used to reduce bleeding. When the body bleeds, it forms clots or plugs as part of healing. In some people these plugs do not stay in place long enough and this can cause too much bleeding. Tranexamic Acid 500 mg Tablets help these plugs to stay in place.

How are Tranexamic Acid 500 mg Tablets used?
The pharmaceutical form of this medicine is tablets and the route of administration is oral (by mouth).

The usual adult dose is 2 to 3 tablets taken 2 to 3 times daily. However, the patient’s doctor may prescribe different doses.

If this medicine is being taken for heavy periods, patients should not take more than 8 tablets (equivalent to 4g) daily. The dose will be reduced in patients who have kidney disease.

The dose for children is worked out according to the patient's body weight. The child’s doctor will advise how long to take this medicine for as this will depend on the child’s condition.

For further information on how Tranexamic Acid 500 mg Tablets are used, refer to the PIL and Summary of Product Characteristics (SmPC) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This medicine can only be obtained with a prescription.

The patient should always take the medicine exactly as their doctor/pharmacist has told them. The patient should check with their doctor or pharmacist if they are not sure.

What benefits of Tranexamic Acid 500 mg Tablets have been shown in studies?
Tranexamic Acid 500 mg Tablets are considered identical to the previously authorised product with the same benefits and risks. No new studies have been provided for Tranexamic Acid 500 mg Tablets, however, reference is made to the studies for the reference product Tranexamic Acid 500 mg Tablets.

What are the possible side effects of Tranexamic Acid 500 mg Tablets?
For the full list of all side effects reported with this medicine, see Section 4 of the PIL or the SmPC available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at https://yellowcard.mhra.gov.ukor search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

Tranexamic Acid 500 mg Tablets is considered to be identical to the previously authorised product with the same benefits and risks.

Why were Tranexamic Acid 500 mg Tablets approved?
The MHRA decided that the benefits of Tranexamic Acid 500 mg Tablets are greater than the risks and recommended that this medicine is approved for use.

What measures are being taken to ensure the safe and effective use of Tranexamic Acid 500 mg Tablets?
As for all newly-authorised medicines, a Risk Management Plan (RMP) has been developed for Tranexamic Acid 500 mg Tablets.

The RMP details the important risks of Tranexamic Acid 500 mg Tablets, how these risks can be minimised, any uncertainties about Tranexamic Acid 500 mg Tablets (missing information), and how more information will be obtained about the important risks and uncertainties.

The following safety concerns have been recognised for Tranexamic Acid 500 mg Tablets:

Summary of safety concerns	
Important identified risks	- Hypersensitivity - Acute venous or arterial thrombosis - Oral contraception - Medical history of a thromboembolic event - Disseminated intravascular coagulation - Visual disturbance - History of convulsions - Haematuria of renal origin - Severe renal impairment (Serum creatinine > 500µmol/1) - Breastfeeding
Important potential risks	- Overdose - Interaction with drugs that exert effects of haemostasis
Missing information	- Paediatric population - Fertility - Pregnancy

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Tranexamic Acid 500 mg Tablets are continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

Other information about Tranexamic Acid 500 mg Tablets
A marketing authorisation was granted in the United Kingdom on 05 May 2023.

The full PAR for Tranexamic Acid 500 mg Tablets follows this summary.

This summary was last updated in July 2023.

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I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the application for Tranexamic Acid 500 mg Tablets (PL 14251/0300) could be approved.

The product is approved for the following indications:

- short-term use for haemorrhage or risk of haemorrhage in increased fibrinolysis or fibrinogenolysis. Local fibrinolysis occurs in the following conditions: prostatectomy, menorrhagia, epistaxis, conisation of the cervix, and traumatic hyphaema
- management of dental extraction in haemophiliacs
- hereditary angioneurotic oedema

The name of the active substance is tranexamic acid. Tranexamic acid is an antifibrinolytic compound which is a potent competitive inhibitor of the activation of plasminogen to plasmin. At much higher concentrations it is a non-competitive inhibitor of plasmin. The inhibitory effect of tranexamic acid in plasminogen activation by urokinase has been reported to be 6-100 times and by streptokinase 6-40 times greater than that of aminocaproic acid. The antifibrinolytic activity of tranexamic acid is approximately ten times greater than that of aminocaproic acid.

This is a national abridged application approved under Regulation 56 of The Human Medicines Regulation 2012, as amended (previously Article 10c of Directive 2001/83/EC, as amended) as an informed consent application. The application cross-refers to the reference product Tranexamic acid 500 mg Tablets, PL 14251/0026.

No new non-clinical or clinical data have been supplied and none are required for this informed consent application.

Suitable justification has been provided for non-submission of an Environmental Risk Assessment (ERA). As the application is for an identical version of an already authorised product, no increase in environmental exposure is anticipated and no ERA is required.

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for this product at all sites responsible for the manufacture, assembly and batch release of this product.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

A national marketing authorisation was granted in the United Kingdom on 05 May 2023

II. EXPERT REPORT

The applicant cross-refers to the data for Tranexamic Acid 500 mg Tablets (also held by Manx Healthcare Limited), to which this application is claimed to be identical. This is acceptable.

III. ASSESSOR'S COMMENTS ON THE PRODUCT INFORMATION SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The SmPC is in line with that for Tranexamic Acid 500 mg Tablets dated December 2021.

PATIENT INFORMATION LEAFLET
Leaflet text has been provided which has been aligned with that for Tranexamic Acid 500 mg Tablets, dated March 2022.

The applicant has committed to submit a leaflet mock-up to the MHRA for approval prior to the product being marketed. This is acceptable.

LABEL
Label text has been provided. The applicant has committed to submit label mock-ups to the MHRA for approval prior to the product being marketed. This is acceptable.

IV. QUALITY ASPECTS

IV.1 Drug Substance

Drug substance specification(s)
The source of the active substance is in line with that for the cross-reference product. The proposed drug substance specification is consistent with the details registered for the cross-reference product.

IV.2. Drug Product

Name
The product has been named in line with current requirements.

Strength, pharmaceutical form, route of administration, container and pack sizes
Tranexamic Acid 500mg Tablets are available in blister packs of white PVC coated with PVdC and hard-tempered aluminium foil on the reverse, in cardboard boxes of 60 tablets.

The appearance of the product is identical to that of the cross-reference product. The proposed shelf life of the product is 3 years with the recommended storage condition ‘Do not store above 25°C’ and ‘Store in the original pack’.

The proposed packaging, shelf life and storage conditions are consistent with the details registered for the reference product.

Legal status
Prescription only medicine (POM).

Manufacturers
The proposed manufacturing site(s) are consistent with the details registered for the cross-reference product and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

Qualitative and quantitative compositions
The composition of the proposed product is consistent with the details registered for the cross-reference product.

Manufacturing process & control of critical steps
The proposed manufacturing processes and process controls are consistent with the details registered for the reference product.

Finished product release/shelf life specifications
The finished product specifications at release and shelf-life are in line with the details registered for the cross-reference product.

TSE Compliance
No excipients of animal or human origin are used in the final products. Confirmation has been provided that the magnesium stearate used in the tablets does not contain any materials of animal or human origin.

This product does not contain or consist of genetically modified organisms (GMO).

V. NON-CLINICAL ASPECTS
As this application is submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended, (as an informed consent application) no new non-clinical data have been supplied and none are required.

VI. CLINICAL ASPECTS
As this application is submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended, (as an informed consent application) no new clinical data have been supplied and none are required.

VII. RISK MANAGEMENT PLAN (RMP)
The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

VIII. USER CONSULTATION
Leaflet text was provided with the application, and the applicant has committed to submit a leaflet mock-up to the MHRA for approval prior to the product being marketed. The applicant also confirmed that any change to the format of the leaflet diverging from the cross-referenced product will be supported by an appropriate user consultation or appropriate bridging study.

IX. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION
The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product. The benefit/risk balance is, therefore, considered to be the same as for the cross-reference product and positive.

The Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling are satisfactory, in line with current guidelines and consistent with the cross-reference product.

In accordance with legal requirements, the current approved UK versions of the SmPC and PIL for this product are available on the MHRA website.

The following text is the currently approved label text. No label mock-ups have been provided for this product. In accordance with legal requirements, this product shall not be marketed until approval of the full-colour label mock-ups has been obtained.

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON BOX

1. NAME OF THE MEDICINAL PRODUCT

Tranexamic Acid 500mg Tablets

2. STATEMENT OF ACTIVE SUBSTANCE(S)

60 tablets each containing tranexamic acid 500mg

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

60 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration.
Please read the enclosed leaflet carefully.
For use as directed by your doctor.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Store in the original pack.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

PL holder:
Manx Healthcare Ltd
Taylor Group House
Wedgnock Lane
Warwick
CV34 5YA
UK

12. MARKETING AUTHORISATION NUMBER(S)

PL 14251/0300

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Tranexamic acid 500mg tablets

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC: {number}
SN: {number}
NN: {number}

TABLE OF CONTENT OF THE PAR UPDATE

Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations where significant changes are made are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPC and/or PIL available on the MHRA website.

Application type	**Scope**	**Product information affected**	**Date of grant**	**Outcome**	**Assessment report attached Y/N**