Saudi Public Assessment Report

(Summary Report)

Kapron®

Type of Application: New Drug Application

Type of Product: Human Generic Drug

Active Ingredient: Tranexamic acid

ATC code: B02AA02

Dosage Form: Film Coated Tablets

Dosage Strength: 500 mg

Pack Size: 20 Tablets

Shelf life: 36 Months

Storage Conditions: Store at temperature not exceeding 30˚ in a dry place

Reference Product in SA (if applicable): Lysteda 650 mg Tablet

Marketing Authorization Holder: Amoun Pharmaceutical Company

Manufacturer: Amoun Pharmaceutical Co., Egypt

Registration No.: 1404221943

Decision and Decision Date: Approved on 4/04/2022

Proposed Indications: Indicated for short-term use for haemorrhage or risk of haemorrhage in those with increased fibrinolysis or fibrinogenolysis. Local fibrinolysis as occurs in the following conditions:

- Prostatectomy and bladder surgery
    - Menorrhagia
    - Epistaxis
    - Conisation of the cervix

- Traumatic hyphaema

- Management of dental extraction in haemophiliacs.
- Hereditary angioneurotic oedema.

Product Background

This product is considered a human generic drug for Saudi regulatory purposes. Furthermore, this product is qualified to follow the SFDA's normal submission regulatory pathway.

The SFDA approval for Kapron® (Tranexamic Acid) is based on a review of the quality, safety and efficacy as summarized hereinafter:

Quality Aspects

Drug Substance

- Tranexamic Acid is a white or almost white crystalline powder. The solubility of tranexamic acid in solvents (Water, Methanol, Toluene, Ethanol, Diethyl Ether and Acetic Acid) is (15 g/100 mL, 0.08 g/100 mL, <0.0001 g/100 mL, 0.001 g/100 mL, <0.0001 g/100 mL and 12 g/100 mL, respectively). Tranexamic Acid does have two chiral centers. Tranexamic acid does not exhibit polymorphism.
- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of Tranexamic Acid has been fully elucidated using several spectroscopic techniques.
- The drug substance specification includes relevant tests for proper quality control. The control methods are validated according to international guidelines.
- Appropriate stability data have been presented and justify the established re-test period.

Drug Product

- The finished product is available as a white to buff oblong biconvex film coated tablet embossed with AK 5 from one side and Amoun from the other side. Each tablet contains 500 mg of Tranexamic Acid. The composition of the drug product is adequately described, qualitatively and quantitatively. Suitable pharmaceutical development data have been provided for the finished product composition and manufacturing process.
- The manufacturing process is described narratively and in sufficient detail, taking into account pharmaceutical development data. Batch manufacturing formulas and in-process controls are included.
- The drug product specification covers appropriate parameters for this dosage form which allow for proper control of the finished drug product. The control methods are validated according to international guidelines. Batch data show consistent quality of the drug product.

- The drug product is packaged in a carton box, containing 2 Alu/PVC blisters, containing 10 tablets in each blister.
- Appropriate stability data have been generated in the packaging material intended for commercial use and following relevant international guidelines. The data show good stability of the finished product and support the shelf life.

Clinical Aspects

Bioequivalence study

Ratio and 90% Confidence Intervals (CI) of Kapron® (Tranexamic Acid) 500 mg versus Cyklokapron® (Tranexamic Acid) 500 mg:

Pharmacokinetic Parameter	Point Estimate (%)	CI 90%
C_{max} (ng/mL)	101.22	94.40 - 108.52
AUC_{0-t} (ng.h/mL)	98.59	93.18 - 104.32
$AUC_{0-\infty}$ (ng.h/mL)	99.15	93.99 - 104.60

Based on the results obtained in this study, Kapron® (Tranexamic Acid) 500 mg of Amoun Pharmaceutical Co., Egypt, is **bioequivalent** to Cyklokapron® (Tranexamic Acid) 500 mg of Pfizer, Australia, under fasting conditions.

Product Information

The approved Summary of Product Characteristics (SPC) with the submission can be found in Saudi Drug Information System (SDI) at: https://sdi.sfda.gov.sa/

The date of revision of this text corresponds to that of the Saudi PAR. New information concerning the authorized medicinal product in question will not be incorporated into the Saudi PAR. New findings that could impair the medicinal product's quality, efficacy, or safety are recorded and published at (SDI or Summary Saudi-PAR report).

For inquiry and feedback regarding Saudi PAR, please contact us at Saudi.PAR@sdfa.gov.sa