الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Saudi Public Assessment Report

(Summary Report)

Eradocin®

Type of Application: New Drug Application.

Type of Product: Human Generic Drug.

Active Pharmaceutical Ingredient(s): Levofloxacin

ATC code: J01MA12

Dosage Form: Film-coated tablet

Dosage Strength: 500 mg, 750 mg

Pack Size: 5

Shelf life: 24 months

Storage Conditions: Store below 30°C.

Reference Product in SA (if applicable): Levox

Marketing Authorization Holder: Alpha Pharma Industry

Note: The Saudi PAR is a final document, which provides information relating to a submission at a particular point in time and will not be updated after publication.

Manufacturer: Alpha Pharma Industry

Registration No.: 2106210813, 2106210812

Date of Decision: 09/06/2020

Proposed Indications:

Levofloxacin 500mg & 750mg Film-coated Tablets is indicated in adults for the treatment of the following infections:

• Acute bacterial sinusitis

• Uncomplicated cystitis

• Acute exacerbation of chronic obstructive pulmonary disease including bronchitis

• Complicated skin and soft tissue infections/complicated skin and skin structure infections

For the above-mentioned infections Levofloxacin 500mg & 750mg Film-coated Tablets should be used only when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the treatment of these infections.

• Acute pyelonephritis and complicated urinary tract infections

• Chronic bacterial prostatitis

• Community-acquired pneumonia

• Inhalation Anthrax: post exposure prophylaxis and curative treatment

Levofloxacin 500mg & 750mg Film-coated Tablets may also be used to complete a course of therapy in patients who have shown improvement during initial treatment with intravenous levofloxacin.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Product Background

This product is considered as a human generic drug for Saudi regulatory purposes qualified to follow the SFDA's regulatory Regular pathway.

The SFDA approval for Eradocin® is based on a review of the quality, safety and efficacy of the product provided as an e-CTD in accordance with the relevant guidelines, basic product information summarized hereinafter:

Drug Substance

- Levofloxacin Hemihydrate is a yellowish white to light yellowish white crystalline powder. Levofloxacin Hemihydrate is Soluble in dimethyl sulphoxide and in acetic acid, sparingly soluble in water, in acetone and in methanol, Practically insoluble glycerin and n-octanol. Polymorphism has been observed (Hemihydrate).
- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of the API has been fully elucidated using several spectroscopic techniques.
- The drug substance specification includes relevant tests for proper quality control. Whereas the control methods are validated according to international guidelines.
- Appropriate stability data have been presented and justify the established re-test period.

Drug Product

- Eradocin drug product is available in two strengths:
    1. 500mg Film Coated Tablets: Peach, oblong embossed JS31 on one side and score line on both the sides, film coated tablets.
    2. 750mg Film Coated Tablets: Yellowish, oblong Embossed JS32 on one side and plain on other side, film coated tablets.
- Each film coated tablet contains 500mg or 750mg of Levofloxacin Hemihydrate . 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 Alu – PVC / PVDC blister in carton.

- 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

The clinical pharmacology, efficacy, and safety of Levofloxacin are well known. According to the regulatory requirements, the applicant has provided a suitable biowaiver study and bioequivalence study is not required for this product.

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