الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Saudi Public Assessment Report

(Summary Report)

JNESTY®

Type of Application: New Drug Application

Type of Product: Human Generic Drug

Active Pharmaceutical Ingredient(s): FUSIDIC ACID

ATC code: D06AX01

Dosage Form: Cream

Dosage Strength: 2%

Pack Size: 1.

Shelf life: 36 Months

Storage Conditions: Store below 30°C

Reference Product in SA: FUCIDIN 2%®

Marketing Authorization Holder: Jedco International Pharmaceutical

Manufacturer: Jedco International Pharmaceutical.

Registration No.: 2408234038

Date of Decision: 24/08/2023

Proposed Indications:

JNESTY 20 mg/g cream is indicated either alone or in combination with systemic therapy, in the treatment of primary and secondary skin infections caused by sensitive strains of Staphylococcus aureus, Streptococcus spp and Corynebacterium minutissimum.
Primary skin infections that may be expected to respond to treatment with fusidic acid applied topically include: impetigo contagiosa, superficial folliculitis, sycosis barbae, paronychia and erythrasma; also such secondary skin infections as infected eczematoid dermatitis, infected contact dermatitis and infected cuts/abrasions.

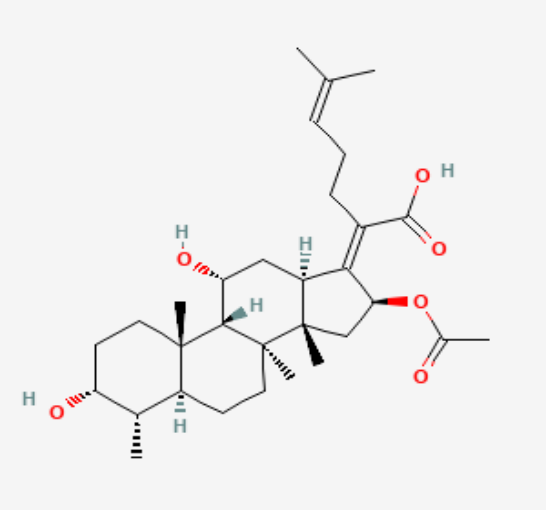
Product Background

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

The SFDA approval for JNESTY® 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

- Fusidic acid is a white or almost white, crystalline powder. Fusidic acid is practically insoluble in water, freely soluble in ethanol (96 per cent). Fusidic acid does have chirality. Polymorphism has been observedas shown in the following structure:



- The drug substance is manufactured by a (multiple-step) chemical synthesis.
- The structure of Fusidic 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 off white homogenous cream. Each tube contains 2% w/w of Fusidic acid (Ph. Eur.). 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 Collapsible Aluminum laminated tube with Aluminum seal containing 30 gm Cream with High density Polyethylene plastic screw white cap.
- 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.
- There are no issues pertaining to drug substance and drug product stability. There are no issues pertaining to drug substance and drug product specifications. All analytical procedures are validated.

Bioequivalence Study

The *in vitro* release studies using franz diffusion cell between Jnesty® (Fusidic acid) 2% cream for Jedco International Pharmaceuticals Co., Egypt versus Fucidin® (Fusidic acid) 2% cream for Leo Laboratories Limited, Berkshire, UK showed similar results.

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