الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Saudi Public Assessment Report

(Summary Report)

Sineo®

Type of Application: New Drug Application.

Type of Product: Human Generic Drug.

Active Pharmaceutical Ingredient(s): Dimethindene Maleate

ATC code: D04AA13

Dosage Form: Oral drops

Dosage Strength: 1 mg/ml

Pack Size: 1

Shelf life: 18 months.

Storage Conditions: Store in refrigerator 2-8 °C, do not freeze

Marketing Authorization Holder: Alpha Pharma Industry

Manufacturer: 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.

Registration No.: 2910234402

Date of Decision:19/10/2023

Proposed Indications:

- Symptomatic treatment of allergic diseases:

Skin: Urticaria, pruritus of various etiology, endogenous eczema with previous medical diagnosis.

Respiratory system: Seasonal (hay fever) and perennial rhinitis with previous medical diagnosis.

- Relieve of itching associated with infectious diseases (e.g. chickenpox) with previous medical diagnosis or after an insect bite or stings.

SINEO is indicated in adults, adolescents and children aged 1 year and older.

SINEO is indicated in allergic rhinitis in adults, adolescents and children aged 6 years and older.

Product Background

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

The SFDA approval for Sineo® 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

- Dimetindene Maleate is a white or almost white, crystalline powder. Dimetindene Maleate is Slightly soluble in water, soluble in methanol. Polymorphism has been observed (art crystalline form).
- 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

- The finished product is available as oral solution. Each 1 ml contains 1 mg of dimetindene maleate. 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 Amber glass type III euro dropper bottle and Black TE screw cap with vertical euro dropper.
- 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.

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