الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Saudi Public Assessment Report

(Summary Report)

Kromafina®

Type of Application: New Drug Application.

Type of Product: Human Generic Drug.

Active Pharmaceutical Ingredient(s): Ondansetron

ATC code: A04AA01

Dosage Form: Film-coated tablet

Dosage Strength: 4 mg, 8 mg

Pack Size: 10

Shelf life: 24 months

Storage Conditions: Store below 30°C

Reference Product in SA (if applicable): Zofran

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.: 2402210541, 2402210540

Date of Decision: 18/02/2021

Proposed Indications:

- Adults:

KROMAFINA tablets are indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy.

KROMAFINA tablets are indicated for the prevention of post-operative nausea and vomiting (PONV). For treatment of established PONV, administration by injection is recommended.

- Paediatric Population:

KROMAFINA is indicated for the management of chemotherapy-induced nausea and vomiting (CINV) in children aged ≥6 months.

No studies have been conducted on the use of orally administered ondansetron in the prevention and treatment of PONV in children aged ≥1 month, administration by IV injection is recommended for this purpose.

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 Kromafina® 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

- Ondansetron hydrochloride is a white to off-white powder. Ondansetron hydrochloride is sparingly soluble in water and in alcohol, soluble in methanol, slightly soluble in methylene chloride. Polymorphism has been observed.
- 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 drug product is available in two strengths:
    1. The 4 mg tablets contain 4 mg of the active ingredient ondansetron and are marked with "JS13" on one face and plain on the other.
    2. The 8 mg tablets contain 8 mg of the active ingredient ondansetron and are marked with "JS18" on one face and plain on the other.
- Each tablet contains 4 mg or 8 mg of ondansetron (as hydrochloride dihydrate). 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 blister packs of 10 tablets comprising aluminium/PVC blister film and aluminium foil lidding.

- 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

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