الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Saudi Public Assessment Report

(Summary Report)

SoiCarby®

Type of Application: New Drug Application.

Type of Product: Human Generic Drug.

Active Pharmaceutical Ingredient(s): Omeprazole, Sodium Bicarbonate

ATC code: A02AH

Dosage Form: Capsule, hard

Dosage Strength: 40,1100 mg

Pack Size: 28

Shelf life: 24 months

Storage Conditions: Store below 30°C

Reference Product in SA (if applicable): Zegerid

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.: 2308234025

Date of Decision:23/08/2023

Proposed Indications:

Duodenal Ulcer:

(omeprazole/sodium bicarbonate) is indicated for short-term treatment of active duodenal ulcer. Most patients heal within four weeks. Some patients may require an additional four weeks of therapy.

Gastric Ulcer

SOICARBY is indicated for short-term treatment (4-8 weeks) of active benign gastric ulcer

Treatment of Gastroesophageal Reflux Disease (GERD)

- Symptomatic GERD

SOICARBY is indicated for the treatment of heartburn and other symptoms associated with GERD for up to 4 weeks.

- Erosive Esophagitis

SOICARBY is indicated for the short-term treatment (4-8 weeks) of erosive esophagitis which has been diagnosed by endoscopy.
The efficacy of SOICARBY used for longer than 8 weeks in these patients has not been established. If a patient does not respond to 8 weeks of treatment, it may be helpful to give up to an additional 4 weeks of treatment. If there is recurrence of erosive esophagitis or GERD symptoms (e.g., heartburn), additional 4-8 week courses of SOICARBY may be considered.

Maintenance of Healing of Erosive Esophagitis

SOICARBY is indicated to maintain healing of erosive esophagitis. Controlled studies do not extend beyond 12 months**.**

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 SoiCarby® 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

Omeprazole:

- Omeprazole is a white or almost white powder. Omeprazole is very slightly soluble in water, soluble in Methylene chloride, sparingly soluble in ethanol (96%) and in methanol. Polymorphism has been observed (Crystalline Form-A).
- 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. The control methods are validated according to international guidelines.
- Appropriate stability data have been presented and justify the established re-test period.

Sodium Bicarbonate:

- Sodium Bicarbonate is a white, crystalline powder. Sodium Bicarbonate is soluble in water; insoluble in alcohol. Polymorphism has not 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. 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 hard-shell gelatin capsule with dark blue opaque cap and white opaque body filled with white to yellowish powder, imprinted "JS58" on cap and "40/1100" on body. Each capsules contains 40mg of Omeprazole and 1100 mg of Sodium Bicarbonate. 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/PE/Aclar blisters 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

Ratio and 90% Confidence Intervals (CI) of SoiCarby® (Omeprazole / Sodium Bicarbonate) 40 mg / 1100 mg versus Zegerid ® (Omeprazole / Sodium Bicarbonate) 40 mg / 1100 mg Capsules:

Pharmacokinetic Parameter	**Point Estimate**	**90% CI**
C_{max}	88.33	78.12 - 99.88
AUC_{0-t}	99.24	91.14 - 108.07
$AUC_{0-\infty}$	99.26	91.24 - 107.99

Based on the results obtained in this study, SoiCarby® (Omeprazole / Sodium Bicarbonate) 40 mg / 1100 mg of Alpha pharma industries, Saudi Arabia, is **bioequivalent** to Zegerid® (Omeprazole / Sodium Bicarbonate) 40 mg / 1100 mg of Salix Pharmaceuticals, a division of Bausch Pharmaceuticals North America LLC Bridgewater, USA 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