الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Saudi Public Assessment Report

(Summary Report)

Sensityn®

Type of Application: New Drug Application.

Type of Product: Human Generic Drug.

Active Pharmaceutical Ingredient(s): Metformin Hydrochloride, Vildagliptin

ATC code: A10BD08

Dosage Form: Film-coated tablet

Dosage Strength: 850,50 mg - 1000,50 mg

Pack Size: 60

Shelf life: 24 months

Storage Conditions: Store below 30°C

Reference Product in SA (if applicable): Galvus met

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.: 1107233857, 1107233858

Date of Decision:11/07/2023

Proposed Indications:

Sensityn is indicated in the treatment of type 2 diabetes mellitus:

- Sensityn is indicated in the treatment of adult patients who are unable to achieve sufficient glycaemic control at their maximally tolerated dose of oral metformin alone or who are already treated with the combination of Vildagliptin and metformin as separate tablets.

- Sensityn is indicated in triple combination therapy with insulin as an adjunct to diet and exercise to improve glycaemic control in adult patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control.

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 Sensityn® 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

Vildagliptin:

- Vildagliptin is a white to off-white crystalline powder. Vildagliptin is Freely soluble in water, slightly soluble in acetone, sparingly soluble in Tetrahydrofuran and practically insoluble in hexane. Polymorphism has been observed (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. Whereas the control methods are validated according to international guidelines.
- Appropriate stability data have been presented and justify the established re-test period.

Metformin:

- Metformin hydrochloride is a white or almost white crystals. Metformin hydrochloride is freely soluble in water, slightly soluble in ethanol (95%), practically insoluble in acetone and in methylene chloride. Polymorphism has been observed (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. 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. 50/1000 mg tablet: (Brown - yellow oval shaped, compound cup convex, film coated tablet, debossed JS22 on one side and plain on other side.).

2. 50/850 mg tablet: (Yellow oval shaped, compound cup convex, film coated tablet, debossed JS23 on one side and plain on other side.).

- Each tablet contains (50mg of vildagliptin and 1000 mg of metformin) or (50mg of vildagliptin and 850 mg of metformin). 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 6 Alu – Alu blisters containing 10 tablets each.
- 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 Sensityn® (Vildagliptin/Metformin) 50/1000mg versus Galvus met® (Vildagliptin/Metformin) 50/1000mg Film coated tablets:

Vildagliptin

Pharmacokinetic Parameter	**Point Estimate**	**90% CI**
C_{max} (ng/mL)	103.90	96.05 - 112.40
AUC_{0-t} (ng/mL)	101.55	97.55 - 105.72
$AUC_{0-\infty}$ (ng/mL)	101.67	98.20 - 105.25

Metformin

Pharmacokinetic Parameter	**Point Estimate**	**90% CI**
C_{max} (ng/mL)	97.15	92.22 - 102.34
AUC_{0-t} (ng/mL)	98.31	93.97 - 102.85
$AUC_{0-\infty}$ (ng/mL)	97.25	93.03 - 101.66

Based on the results obtained in this study, Sensityn® (Vildagliptin/Metformin) 50/1000mg of Alpha pharma industries, Saudi Arabia is **bioequivalent** to Galvus met® (Vildagliptin/Metformin) 50/1000mg of Novartis Pharma, Switzerland, under fed 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