الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Saudi Public Assessment Report

(Summary Report)

Gleptal ®

Type of Application: New Drug Application.

Type of Product: Human Generic Drug

Active Pharmaceutical Ingredient(s): Vildagliptin

ATC code: A10BH02

Dosage Form: Tablet

Dosage Strength: 50 mg.

Pack Size: 30

Shelf life: 24 months.

Storage Conditions: Do not store above 30°C

Reference Product in SA (if applicable): Galvus®

Marketing Authorization Holder: Al-Taqaddom pharmaceutical Industries

Manufacturer: Al-Taqaddom pharmaceutical Industries

Registration No.: 5-5187-20

Date of Decision: 23/02/2020

Proposed Indications: Vildagliptin is indicated in the treatment of type 2 diabetes mellitus in adults:

As monotherapy

- in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.

As dual oral therapy in combination with

- metformin, in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin,
- a sulphonylurea, in patients with insufficient glycaemic control despite maximal tolerated dose of a sulphonylurea and for whom metformin is inappropriate due to contraindications or intolerance,
- a thiazolidinedione, in patients with insufficient glycaemic control and for whom the use of a thiazolidinedione is appropriate.

As triple oral therapy in combination with

- a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.

Vildagliptin is also indicated for use in combination with insulin (with or without metformin) when diet and exercise plus a stable dose of insulin 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 Gleptal® 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:

Quality Aspects

Drug Substance

- Vildagliptin is a while to off-white crystalline powder.. Vildagliptin is freely soluble in water, Methanol, Dichloromethane, Chloroform and Dimethyl formamide and Sparingly soluble in Acetone . Polymorphism has been observed (crystalline Form).
- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of Vildagliptin 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 White to off white with yellowish speckling round biconvex tablet engraved with (TQ) on one side and plain on the other side. Each tablet contains 50 mg of Vildagliptin. 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 three Alu/Alu blisters each containing 10 tablets.
- 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 Gleptal® (Vildagliptin) 50 mg Tablet versus Galvus ® (Vildagliptin) 50 mg Tablet:

Pharmacokinetic Parameter	**Point Estimate**	**90% CI**
C_{max}	91.63	84.04-99.9
AUC_{0-t}	98.95	95.32-102.71
$AUC_{0-\infty}$	98.96	95.44-102.6

Based on the results obtained in this study, Gleptal® (Vildagliptin) 50 mg Tablet of AL Taqaddom Pharmaceutical Ind., Jordan, is **bioequivalent** to Galvus ® (Vildagliptin) 50 mg Tablet of Novartis Pharma Stein AG, (Switzerland), 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