الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Saudi Public Assessment Report

(Summary Report)

Helt®

Type of Application: New drug application.

Type of Product: Human generic drug.

Active Pharmaceutical Ingredient(s): Tadalafil.

ATC code: G04BE08.

Dosage Form: Film-coated tablet.

Dosage Strength: 20 – 10 – 5 mg.

Pack Size: 30.

Shelf life: 24 months.

Storage Conditions: Do not store above 30°C.

Reference Product in SA (if applicable): Cialis 20 mg Film-coated tablet.

Marketing Authorization Holder: Pharma International Company.

Manufacturer: Pharma International Co.

Registration No.: 290922267.

Date of Decision: Approved on 03/10/2022.

Proposed Indications: Treatment of erectile dysfunction in adult males. In order for tadalafil to be effective for the treatment of erectile dysfunction, sexual stimulation is required. 5 mg only: Treatment of the signs and symptoms of benign prostatic hyperplasia in adult males. Helt is not indicated for use by women.

Product Background

This product is considered as a human generic drug, for Saudi regulatory purposes. Furthermore, this product is qualified to follow the SFDA's regulatory pathway regular submission.

The SFDA approval for Helt® (Tadalafil 20, 10, 5 mg) is based on a review of the quality, safety and efficacy as summarised hereinafter:

Quality Aspects

Drug Substance

- Tadalafil is a white or almost white powder. Tadalafil is practically insoluble in water, freely soluble in dimethyl sulfoxide, slightly soluble in methylene chloride. Tadalafil structure contains two chiral carbons in its structure as indicated and is optically active that rotates the plane polarized light in clockwise direction, one isomer is manufactured and specified. Polymorphism has been observed.
- The drug substance (DS) is manufactured by a multiple-step chemical synthesis.
- The structure of Tadalafil 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 in three strengths:
    1. 5 mg film coated tablets: Peach normal round biconvex film coated tablets engraved with (PhI) on one face.
    2. 10 mg film coated tablets: Peach film coated round biconvex tablets engraved with (PhI) on one face and scored on the other side.
    3. 20 mg film coated tablets: Peach 7.5mm x 12.2mm Almond shape tablets engraved with PhI on one face and VF3 on the other one.
- Each tablet contains:
    1. 5 mg of Tadalafil
    2. 10 mg of Tadalafil
    3. 20 mg of Tadalafil

- The composition of the drug product (DP) 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. Satisfactory validation data pertaining to the commercial manufacturing process are provided.
- 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 (PVC/PVDC) Aluminum blisters.
- 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

Bioequivalence study under fasting conditions:
Ratio and 90% Confidence Intervals (CI) of Helt® (Tadalafil) 20 mg versus Cialis® (Tadalafil) 20 mg:

Pharmacokinetic Parameter	**Point Estimate**	**90% CI**
C_{max} (ng/mL)	95.10	89.12 – 101.47
AUC_{0-t} (ng/mL)	99.34	92.23 – 107.00
$AUC_{0-\infty}$ (ng/mL)	100.37	93.29 – 107.98

Bioequivalence study under fed conditions:
Ratio and 90% Confidence Intervals (CI) of Helt® (Tadalafil) 20 mg versus Cialis® (Tadalafil) 20 mg:

Pharmacokinetic Parameter	**Point Estimate**	**90% CI**
C_{max} (ng/mL)	106.44	99.65 – 113.69
AUC_{0-t} (ng/mL)	109.38	101.05 – 118.39
$AUC_{0-\infty}$ (ng/mL)	107.83	100.38 – 115.82

Based on the results obtained in these studies, Helt® (Tadalafil) 20 mg of Pharma International company, Jordan, is bioequivalent to Cialis® (Tadalafil) 20 mg of Lilly S.A., Spain, under fasting and 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