الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Saudi Public Assessment Report

(Summary Report)

Talynta®

Type of Application: New Drug Application.

Type of Product: Human Generic Drug.

Active Pharmaceutical Ingredient(s): Dapoxetine

ATC code: G04BX14

Dosage Form: Film-coated tablet

Dosage Strength: 30 mg, 60 mg

Pack Size: 4

Shelf life: 24 months

Storage Conditions: Store below 30°C

Reference Product in SA (if applicable): Priligy

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.: 1609211063, 1609211064

Date of Decision:09/09/2021

Proposed Indications:

TALYNTA is indicated for the treatment of premature ejaculation (PE) in adult men aged 18 to 64 years.

TALYNTA should only be prescribed to patients who meet all the following criteria:

• An intravaginal ejaculatory latency time (IELT) of less than two minutes; and

• Persistent or recurrent ejaculation with minimal sexual stimulation before, on, or shortly after penetration and before the patient wishes; and

• Marked personal distress or interpersonal difficulty as a consequence of PE; and

• Poor control over ejaculation; and

• A history of premature ejaculation in the majority of intercourse attempts over the prior 6 months.

TALYNTA should be administered only as on-demand treatment before anticipated sexual activity. TALYNTA should not be prescribed to delay ejaculation in men who have not been diagnosed with PE.

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 Talynta® 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

- Dapoxetine Hydrochloride is a white to off-white powder. Dapoxetine Hydrochloride is Soluble in methanol and water. 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

- Talynta drug product is available in two strengths:
    1. 30 mg film coated tablet: (Round, convex, film coated tablets with upper - "JS2" and lower - plain).
    2. 60 mg film coated tablet: (Round, convex, film coated tablets with upper - "JS3" and lower - plain).
- Each tablet contains 30 mg or 60 mg of Dapoxetine Hydrochloride. 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/PVCD blister.
- 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 Talynta® (Dapoxetine) 60 mg versus Priligy® (Dapoxetine) 60 mg Tablets:

Pharmacokinetic Parameter	**Point Estimate**	**90% CI**
C_{max}	102.87	93.84 - 112.78
AUC_{0-t}	108.39	100.24 - 117.21
$AUC_{0-\infty}$	107.85	100.19 - 116.09

Based on the results obtained in this study, Talynta® (Dapoxetine) 60 mg of Alpha pharma industries, Saudi Arabia, is **bioequivalent** to Priligy® (Dapoxetine) 60 mg of Menarini- Von Heyden GmbH, Germany, 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