TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR PRILIGY (DAPOXETINE HYDROCHLORIDE 60 MG) FILM COATED TABLETS

Version number 1

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1. Introduction

Priligy is an innovator product containing the active substance Dapoxetine hydrochloride. Dapoxetine hydrochloride, belonging to a class of drugs known as selective serotonin reuptake inhibitors with ATC code G04BX14. Serotonin is thought to play a role in ejaculatory reflex mediation and is believed to act centrally and peripherally to inhibit ejaculation, perhaps via the serotonin (5HT)1a receptor.

The applicant has applied for the following indications: Priligy is indicated for the treatment of premature ejaculation (PE) in adult men aged 18 to 64 years.

The applied indications have been approved in Tanzania.

1.1 Product details

Registration number	TAN 21 HM 0116
Brand name	Priligy
Generic name, strength and form	Dapoxetine Hydrochloride 60 mg film coated tablets
ATC classification	G04BX14: Other urologicals
Distribution category	POM
Country of origin	Germany
Associated product	Priligy (Dapoxetine Hydrochloride 30 mg) film coated tablets registered with registration number TAN 20 HM 0628
Marketing Authorization Holder	Berlin-Chemie AG (Menarmi Group), Glienicker Weg 125, 12489, Berlin, Germany. E-Mail: prijli@menarini.it
Local Technical Representative	Phillips Pharmaceuticals (Tanzania) Ltd, Vingunguti Industriai Area, Nyerere Road, P.O. Box 737, Dar Es Saalam, Tanzania. E-Mail: kunal.assar@phillipstanzania.co

1.2 Assessment procedure

The application for registration of Priligy was submitted on 12 October, 2018. The product underwent abridged assessment. Assessment was completed in 3 (three) rounds of evaluation. Priligy was registered on <29/03/2021 >

1.3 Information for users

Visual description of the finished product	Grey, circular, convex, film-coated tablets debossed with 60 inside a triangle on one side and blank on the other side
Primary packing material	Alu/PVC/PE/PVDC blister pack of 3 tablets
Secondary packing materials	1 blister is packed in a printed carton box
Shelf-life and storage condition	36 months
Route of administration	Oral
Therapeutic indications	Priligy is indicated for the treatment of premature ejaculation (PE) in adult men aged 18 to 64 years

2. Labelling and product information

Summary of product characteristics
The SmPC included all the relevant information to ensure correct and safe use of the medicine by healthcare providers. The complete SmPC can be accessed here.

Package insert/leaflet
The package insert is confirmed to be derived from the SmPC and contains sufficient data for the end user. Since the product is POM, the package insert contains full prescribing information as per SmPC and simplified information for patients.

Container labels
The product label information is presented in English. Details in the secondary pack label include:
Brand name: Priligy 60 mg film-coated tablets
Composition: Each tablet contains 60 mg dapoxetine as a hydrochloride salt
Pack size: 3 tablets
Manufacturing details: batch number, manufacturing date and expiry date are indicated.
Storage conditions: Store below 30^0C
Manufacturer address: Menarini - Von Heyden GmbH (M H) Leipziger Strasse 7-13, 01097, Dresden
Germany
Unique identifier: TMDA registration number
Special warnings/precautions or instructions for use: Excipient of safety concern i.e Lactose has been indicated; more special warnings have been provided in the package insert which has recommended to be read before the use of the product

The details of the primary pack include:
Brand name and strength: Priligy 60 mg film-coated tablets
Manufacturing details: batch number, manufacturing date and expiry date are indicated
Name of manufacturer: Menarini - Von Heyden GmbH (M H), Germany

The content of the primary and secondary labels was aligned to the requirements of the Part V of the Compendium: Guidelines on Format and Content of Product Labels for Medicinal products. The label contains sufficient information for proper identification of the medicine and post marketing follow up of the product.

Mock labels are currently not available.

3. Scientific discussion

Quality of Active Pharmaceutical Ingredient(s)

Information on quality of the API was submitted in form of Full details in the product dossier.

General properties

Dapoxetine hydrochloride is a new chemical entity which is presented as the S enantiomer, it has the following chemical names:

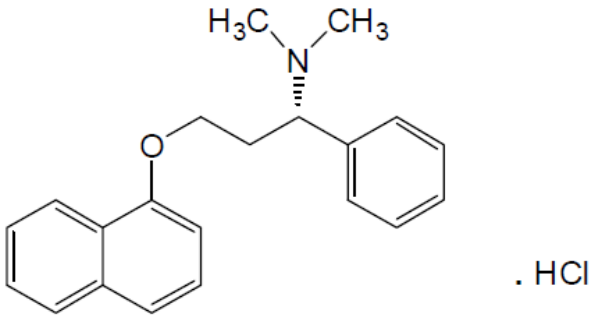
I. (S)-N,N-dimethyl-3-(naphthalen-1-yloxy)-1-phenylpropan-1-amine hydrochloride;

II. (αS)-N,N-dimethyl-α-[2-(1-naphthalenyloxy)ethyl]benzenemethanamine hydrochloride;

III. (+)-N,N-dimethyl-1-phenyl-3-(1-naphthalenyloxy)propanamine hydrochloride;

IV. (+)-(S)-N,N-dimethyl-alpha-[2-(1-naphthyloxy)ethyl]benzylamine hydrochloride.

The molecular formula of Dapoxetine hydrochloride is C21H23NO.HCl and it has the following structure:



General properties

Dapoxetine hydrochloride is a white or almost white crystalline powder. It exhibits polymorphism. The active substance manufacturer is consistently manufacturing the same polymorphic form. Polymorphic form control has been included in the active substance specification. Dapoxetine Hydrochloride is very soluble in methanol, chloroform, sparingly soluble in acetone and practically insoluble in water.

Critical physico-chemical properties of the API were solubility, particle size and polymorphism.

Manufacture

Dapoxetine API manufacturer is Olon S.p.A.* located at Via Livelli, 1, 26852 Casaletto Lodigiano, Frazione Mairano, LODI, Italy. The manufacturing complies with GMP requirements as evidenced by the GMP certificate issued by AIFA - Italian Medicines Agency. Dapoxetine API is manufactured by chemical synthesis using conventional techniques. Sufficient controls of quality of materials and in-process checks were employed throughout the manufacturing process.

Specifications

The API Dapoxetine specifications were set as per in-house standards and ICH guidelines. The parameters monitored during quality control are: appearance, identification (IR, HPLC, Chlorides), specific optical rotation, appearance of solution, loss on drying, sulphated ash, heavy metals, r-enantiomer (HPLC), related substances (HPLC), residual solvents (GC) and assay (HPLC). Satisfactory justification for excluding test for polymorphism and particle size distribution was provided. Compliance to these specifications were established via batch analysis data and stability studies.

Stability and container closure system
The re-test period of Dapoxetine API is 60 months when packed in transparent polyethylene bag and stored at or below storage conditions.

Quality of the Finished Pharmaceutical Product

Formulation

Priligy is a grey, circular, convex, film-coated tablets debossed with 60 inside a triangle on one side and blank on the other side. The tablets are packed in a Alu/PVC/PE/PVDC blister of 3 tablets, such blister is packed in a printed carton along with a package leaflet.

Priligy dosage form is film-coated tablets containing Depoxetine Hydrochloride equivalent to Depoxeline 60 mg.

The excipients are: Lactose Monohydrate, Microcrystalline Cellulose, Croscarmellose Sodium, Colloidal Anhydrous Silica, Magnesium Stearate and coating powder grey.

The quantities of all ingredients are confirmed to be in line with the recommendations of Handbook of Pharmaceutical Excipients, 7th Edition in terms of function and quantities. The formulation contains Lactose which is of safety concern therefore appropriate warnings are included in the product label and summary of product characteristics (SmPC).

Manufacture

The finished product manufacturer is Menarini - Von Heyden GmbH (MvH) located at Leipziger Strasse 7-13 01097, Dresden, Germany. The manufacturing site complies with TMDA cGMP standards.

Specifications

The FPP is non-compendia. The manufacturer controls the quality of the finished product as per in-house standards and ICH requirements. The parameters monitored during quality control are: Appearance, Identification, Assay, identification for colouring agent, Dissolution, Uniformity of dosage units, related substances and microbial tests. Compliance to the standard was established using batch analysis data and stability data.

Stability and container closure system
Stability studies were conducted on 3 (three) batches of the finished product stored at 30 ± 2°C & RH: 75 ± 5% RH for 36 months and 40± 2°C & RH: 75% ± 5% RH for 6 months. Based on the stability data presented, the approved shelf-life is 36 months when stored in Alu/PVC/PE/PVDC blister pack of 3 tablets at or below 30◦C.

Safety and efficacy information

The finished product Priligy 60 mg film-coated tablets has been approved in different countries which are recognized by TMDA as countries with competent regulatory authority including Sweden, Germany and Italy. Data submitted to establish safety and efficacy of the finished product was not reviewed as the same has been reviewed and approved by recognized countries. Therefore, safety and efficacy of Priligy 60 mg film-coated tablets was established based on the approval of the product in the mentioned countries above.

4. Benefit-Risk Assessment and Conclusion

On basis of the data submitted, the current state of knowledge and compliance to Good Manufacturing Practice, the benefit of the product outweighs the risks associated with its use when used in accordance to the summary of product characteristics. Priligy 60 mg film-coated tablets is recommended for registration.

5. Post-approval updates

Variation applications

Reference number	Date submitted	Change requested	Recommendation	Granting date

Feedback from pharmacovigilance, post marketing surveillance and enforcement activities

Type of feedback	Impact	Response

Re-registration applications

NA

PART 5: CHANGE HISTORY

Version number	Date	Description of update	Section(s) Modified	Approval date

Annex I: Mock up label