THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES ANDMEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR ANDROGEL (TESTOSTERONE 16.2 MG/G) GEL

Version number 1.0
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TMDA Headquarters, Plot No. 56/1, Block E, Kisasa B Centre, Hombolo Road, P. O. Box 1253, Dodoma - Tanzania,
Tel: +255 (26) 2961989/2061990/ +255(22) 2450512/2450751/2452108,
Email: info@tmda.go.tz, Website: www.tmda.go.tz, Toll free: 08001100834

1. Introduction

Androgel is a generic medicine of Testosterone gel. Androgel is an androgen medicine medicine belonging to G03B A03- Androgens. Androgel exerts is activity by replacement of endogenous testosterone. Androgel is approved in Tanzania for use in adults.

1.1 Product details

Registration number	TAN 20 HM 0407
Brand name	Androgel
Generic name, strength and form	Testosterone 16.2 mg/g gel
ATC classification	G03B A03- Androgens
Distribution category	POM
Country of origin	France
Associated product	State any other product of formulation, strength or site that is linked or associated with the product if applicable
Marketing Authorization Holder	BESINS HEALTHCARE SA, Avenue Louise 287, B-1050 Brussels Belgium, Belgium. E-mail: information@besins-healthcare.com
Local Technical Representative	Laborex Tanzania Limited CFAO Motor Complex, P.O. Box 70032, Sokoine, Plot No. 89-90 Nyerere Road, Dar es Salaam, Country: Tanzania.

1.2 Assessment procedure

The application for registration of Androgel was submitted on 25/04/2019. The product underwent abridged assessment. Assessment was completed in 2 rounds of evaluation. Androgel was registered on 25/09/2020.

1.3 Information for users

Visual description of the finished product	Transparent or slightly opalescent colourless gel
Primary packing material	Polypropylene canister
Secondary packing materials	
Shelf-life and storage condition	36 months Do not store above 30°C
Route of administration	Topical
Therapeutic indications	ANDROGEL 16.2 mg/g, gel is indicated in adults as replacement therapy for male hypogonadism when testosterone deficiency has been clinically and biologically confirmed

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 simplified information for patients.

Container labels
The product label information is presented in <English/Swahili>. Details in the secondary pack label include:
Brand name:
Composition: <generic name & strength, list of excipients (if applicable)>
Pack size: <primary & secondary pack>
Manufacturing details: <batch number, manufacturing date, expiry date>
Storage conditions: <state the condition as it appears on the label>
Manufacturer address: <physical address of release site>
Unique identifier: <state the unique identification used>
Special warnings/precautions or instructions for use: <include warnings or IFU if applicable>

The details of the primary pack include:
Brand name and strength:
Manufacturing details: <batch number, manufacturing date, expiry date>
Name of manufacturer: <name only>

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.
Describe any approved deviation to the requirements and the justification for the deviation.

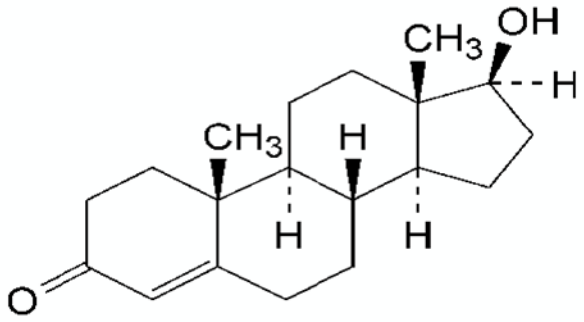
3. Scientific discussion

Quality of Active Pharmaceutical Ingredient(s)

Information on quality of the API was submitted in form of CEP.

General properties
Testosterone API is compendia in BP/Ph.Eur.
Molecular formula: $C_{19}H_{28}O_2$
Chemical name: Androst-4-en-3-one, 17-hydroxy-, (17ß)

Structure:



Critical physico-chemical properties of the API were practically insoluble in water, freely soluble in alcohol and in methylene chloride, practically insoluble in fatty oils.

Manufacture

The API manufacturing site, Productos Quimicos Naturales SA de CV (PROQUINA) Ojo De Agua Domicilio Conocido Ixtaczoquitlan Veracruz 94450, Mexico OR Bayer Pharma AG Ernst-Schering Strasse 14, Bergkamen 59192, Germany was noted to comply with WHO GMP requirements as evidenced by the GMP certificate issued by <state the issuing authority>. Testosterone 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 specifications were set as per BP/Ph.Eur standards and ICHQ3A. The parameters monitored during quality control are: description, identification, specific optical rotation, impurities D and F, related substances, loss on drying and assay. Compliance to these specifications was established via batch analysis data and stability studies.

Stability and container closure system

The re-test period of Testosterone API is 12 months when packed in polyethylene bags and laminated with aluminium and stored at below 30ºC.

Quality of the Finished Pharmaceutical Product

Formulation

Androgel is a transparent or slightly opalescent colourless gel. Androgel contains Testosterone and other ingredients listed hereafter isopropyl myristate, ethanol, carbomer (Carbopol 980), sodium hydroxide and purified water. The quantities of all ingredients are confirmed to be in line with the recommendations of Handbook of Pharmaceutical Excipients, Edition 8th in terms of function and quantities. Ingredient, <excipient> is of safety concern therefore appropriate warnings were included in the product label.

Manufacture

The finished product was manufactured at Laboratoires Besins International, 13, rue Périer 92120 Montrouge, France. The compliance of the site to TMDA GMP standards was confirmed through <site inspection/desk-review> on <date of GMP compliance>.

Specifications

The FPP is compendia in BP. The manufacturer controls the quality of the finished product as per BP/in-house and ICHQ3B requirements. The parameters monitored during quality control are: appearance, identification, pH, viscosity, assays,related substances, uniformity of mass of delivered doses, number of doses delivered, extractable content 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 batches of the finished product stored at 30°C / 75% RH for 36 months and 40°C / 75% RH for 6 months. Based on the stability data presented, the approved shelf-life is 36 months when stored in low density polyethylene (LDPE)/aluminium pouch at below 30°C.

Safety and efficacy information

Safety and efficacy of Androgel was established through reliance on the innovator product.

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. Androgel 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

Application for renewal of registration was submitted on <DDMMYYYY>. The application was finalized in <number> rounds of evaluation. The product was confirmed to still be compliant to the standards of quality, safety and efficacy, hence registration was renewed on <DDMMYYYY>.

PART 5: CHANGE HISTORY

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

Annex I: Mock up label