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MINISTRYOFHEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR TELMINORM-40 (TELMISARTAN 40 MG) TABLETS

Version number 1.0
09 October 2023

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1. Introduction

Telminorm-40 is a generic medicine of Telmisartan 40 mg tablets. Telminorm-40 is an antihypertensive medicine belonging to C09CA07-Angiotensin II Antagonists, plain group. Telminorm-40 exerts activity by antagonizing angiotensin II receptor (type AT1.Telminorm-40 is approved in Tanzania for use in adults.

1.1 Product details

Registration number	TAN 20 HM 0202
Brand name	Telminorm-40
Generic name, strength and form	Telmisartan 40 mg tablets
ATC classification	C09CA07-Angiotensin II Antagonists, plain
Distribution category	POM
Country of origin	India
Associated product	NA
Marketing Authorization Holder	Ipca Laboratories Limited 48, Kandivli Industrial Estate, Kandivli (West), Mumbai – 400 067 Country: India E-Mail: Ipca@ipca.com
Local Technical Representative	Philips Pharmaceuticals (Tanzania) Limited Plot No 111, RK Complex, Dar es salaam, Tanzania. Telephone: +255 782 573741 Email: anant.bhalani@phillipstanzania.com

1.2 Assessment procedure

The application for registration of Telminorm-40 was submitted on 19/04/2017. The product underwent full assessment. Assessment was completed in 3 rounds of evaluation. Telminorm-40 was registered on 25/07/2020.

1.3 Information for users

Visual description of the finished product	White to off-white, round, biconvex, uncoated tablets plain on both sides'
Primary packing material	Aluminium/aluminium blisters (PA/Al/PVC/Al)
Secondary packing materials	1 x 3's blisters packed in a carton along with pack insert
Shelf-life and storage condition	24 months Store below 30°C
Route of administration	Oral
Therapeutic indications	Is indicated for the treatment of hypertension, it may be used alone or in combination with other

	antihypertensive agents. Is also indicated for reduction of the risk of myocardial infarction, stroke, or death from cardiovascular causes in patients 55 years of age or older at high risk of developing major cardiovascular events that are unable to take ACE inhibitors

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 that is intended for long term use, the package insert contains full prescribing information as per SmPC.

Container labels

The product label information is presented in English. Details in the secondary pack label include:
Brand name: Telminorm-40
Composition: Telmisartan 40 mg tablets)
Pack size: 3 × 10
Manufacturing details: batch number, manufacturing date, expiry date
Storage conditions: Store below 30°C
Manufacturer address: Ipca Laboratories Limited 48, Kandivli Industrial Estate, Kandivli (West), Mumbai – 400 067,India.
Unique identifier: NA
Special warnings/precautions or instructions for use: none

The details of the primary pack include:
Brand name and strength: Telminorm-40
Manufacturing details: batch number, manufacturing date, expiry date
Name of manufacturer: Ipca Laboratories Limited

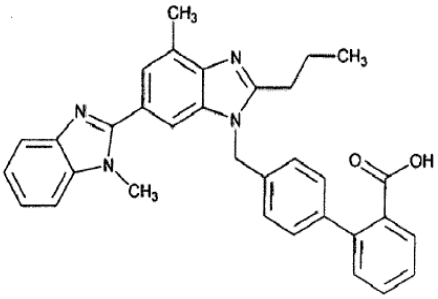
The content of the primary and secondary labels was aligned to the requirements of the Part V of the Compendium: Guidelines on Format and Content of Product Labels for Medicinal products. The label contains sufficient information for proper identification of the medicine and post marketing follow up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

General properties
Telmisartan API is compendia in USP.
Molecular formula: $C_{33}H_{30}N_4O_2$
Chemical name: [1,1'-Biphenyl]-2-carboxylic acid, 4'-[(1,4'-dimethyl-2'- propyl[2,6' -bi-1H-benzimidazol]-1' -yl)methyl-]
Structure:



Critical physico-chemical properties of the API were sparingly soluble in methylene chloride, slightly soluble in methanol, practically insoluble in water.

Manufacture
The API manufacturing site, Ipca Laboratories Limited, Sejavta, Ratlam 457 002, Madhya Pradesh, India was noted to comply with WHO GMP requirements as evidenced by the GMP certificate issued by Food & Drugs Administration Madhya Pradesh.Telmisartan 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 USP standards and ICHQ3A. The parameters monitored during quality control are:

appearance, identification, loss on drying, residue on ignition, heavy metals, organic impurities, residual solvent and assay. Compliance to these specifications were established via batch analysis data and stability studies.

Stability and container closure system
The re-test period of Telmisartan API is 60 months when packed in inner clear and outer black LDPE Bag then packed in fiber drum / HMHDPE Drum and sealed with locking seal and stored below 30°C.

Quality of the Finished Pharmaceutical Product

Formulation

Telminorm-40 is a white to off-white, round, biconvex, uncoated tablets plain on both sides. Telminorm-40 contains Telmisartan and other ingredients listed hereafter sodium hydroxide, meglumine, povidone, mannitol, purified water, magnesium stearate. 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..

Manufacture

The finished product was manufactured at Ipca Laboratories Limited, Sejavta, Ratlam 457 002, Madhya Pradesh. India. The compliance of the site to TMDA GMP standards was confirmed through site inspection on 12 and 13 October 2016.

Specifications

The FPP is compendial in USP. The manufacturer controls the quality of the finished product as per USP and ICHQ3B requirements. The parameters monitored during quality control are: description, identification, average weight of tablets, uniformity of weight, uniformity of dosage units (by content uniformity), disintigration, assay, dissolution, organic impurities and microbial testing. 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 ± 2°C/75 ± 5 % RH for 18 months and 40 ± 2°C/75 ± 5 % RH for 6 months. Based on the stability data presented, the approved shelf-life is 24 months when stored in Alu-Alu blister strip pack at 30°C.

Safety and efficacy information

Safety and efficacy of Telminorm-40 was established through biowaiver application/clinical trial. Comparative dissolution report number <number> was submitted.

In case of biowaiver

The biowaiver was approved based on additional strength.

Telminorm-40 fulfilled the criteriafor waiving an in-vivo bioequivalence study as per relevant TMDA guidance. Dissolution profiles of Telminorm-40 tablets was compared to Telminorm-80 tablets.<At least/less than> 85% of the labelled amount of <molecule> had dissolved in all three media. Therefore, <confirming similarity/necessitating calculation of similarity factor f2, which was noted to be above 50>.

4. Benefit-Risk Assessment and Conclusion

On basis ofthe 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. <Brand name> 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

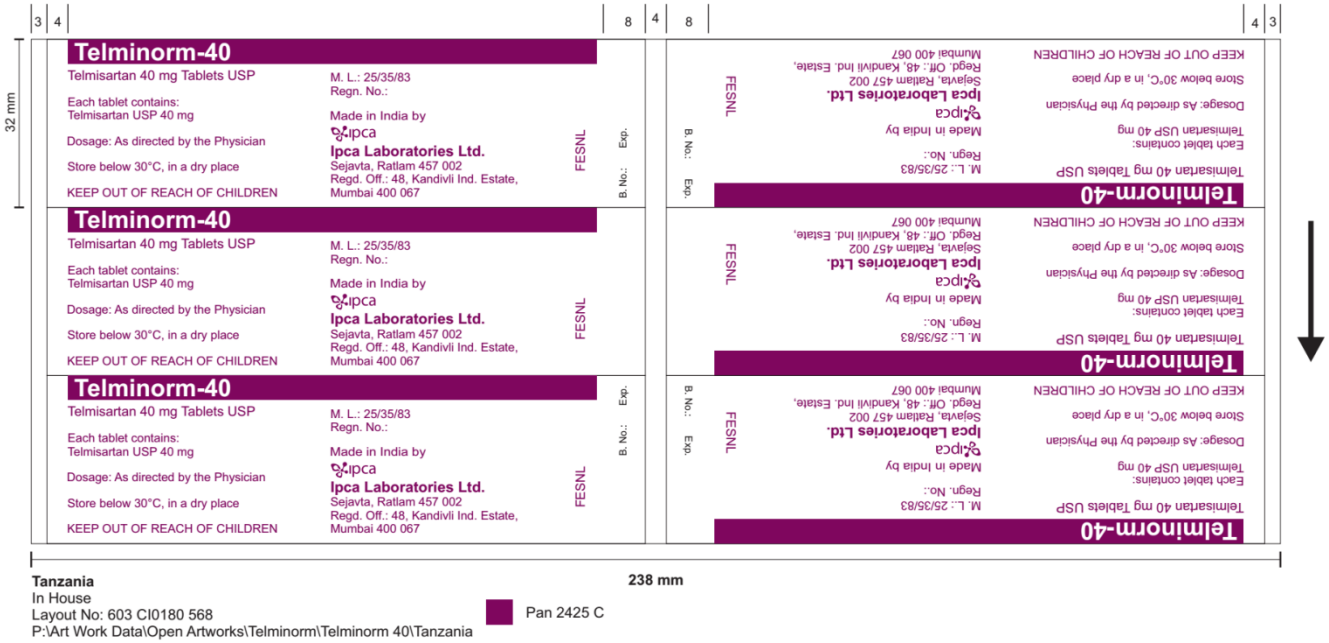
Re-registration applications

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>.

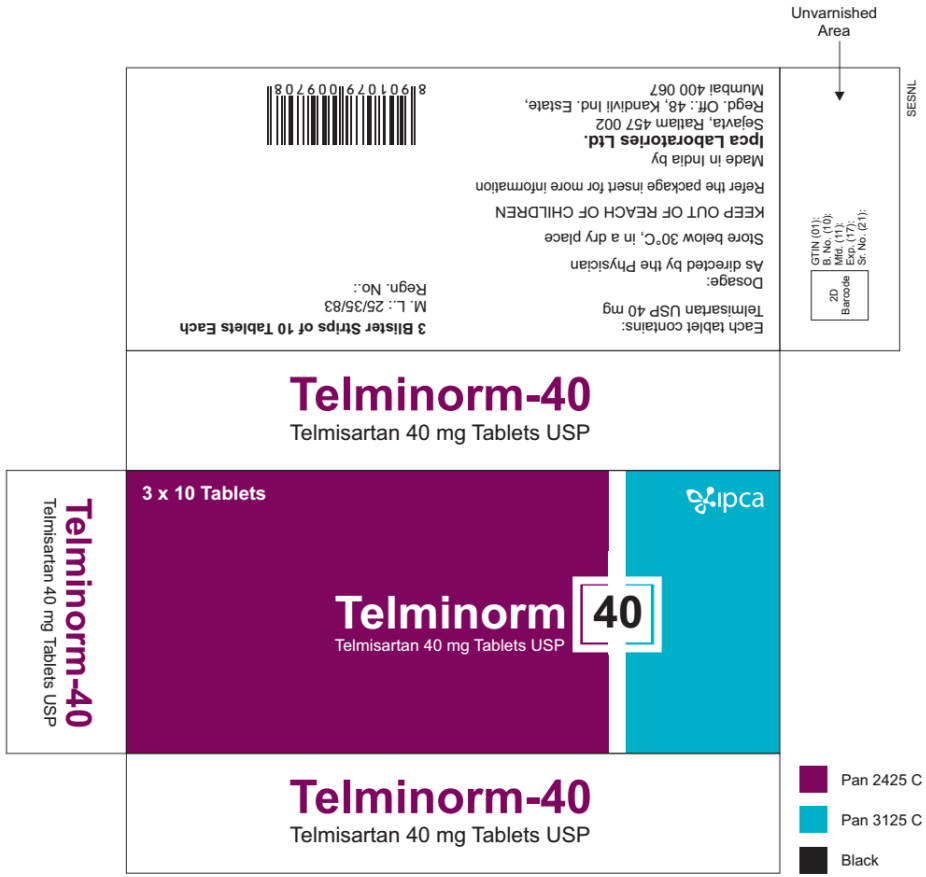
PART 5: CHANGE HISTORY

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

Annex I: Mock up label



Effective date: 03/10/2022



Tanzania
In House
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Size: 120 x 22 x 52 mm