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MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR OSMOWIN (LACTULOSE 66.66%W/V) 200 ML SOLUTION

Version number 1.0
21 October 2023

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1. Introduction

Osmowin is a generic medicine of Lactulose oral solution. Osmowin is a laxative medicine belonging to A06AD11- Osmotically acting laxatives group. Osmowin exerts is activity by stimulating peristalsis of the colon and returning the consistency of the stool leading to clearance of constipation. Osmowin is approved in Tanzania for use in adults and children.

1.1 Product details

Registration number	TAN 20 HM 0416
Brand name	Osmowin
Generic name, strength and form	Lactulose oral solution
ATC classification	A06AD11- Osmotically acting laxatives
Distribution category	POM
Country of origin	India
Associated product	State any other product of formulation, strength or site that is linked or associated with the product if applicable
Marketing Authorization Holder	Win-Medicare Pvt Ltd 1311, Modi Tower, 98, Nehru Place, New Delhi 110019 India Email: madhur.singh@winmedicare.com
Local Technical Representative	Phillips Distributors Ltd, P.O. Box 737, Dar es Salaam, Tanzania. Email: ananti.bhalani@phillipstanzania.com

1.2 Assessment procedure

The application for registration of Osmowin was submitted on 18/12/2015. The product underwent full assessment. Assessment was completed in 3 rounds of evaluation. Osmowin was registered on 25/09/2020.

1.3 Information for users

Visual description of the finished product	Colourless or Pale Yellow to Amber Coloured Syrup Liquid with Sweet taste having Lemon Flavour
Primary packing material	Amber Coloured PET Bottle of 100ml & 200ml
Secondary packing materials	
Shelf-life and storage condition	24 Months Store below or at 30˚C
Route of administration	Oral
Therapeutic indications	Management of Constipation

	Management of Hepatic Encephalopathy

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 both 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: Osmowin
Composition: Lactulose solution
Pack size: 100 ml/200 ml
Manufacturing details: batch number, manufacturing date, expiry date
Storage conditions: Store at or below 30˚C
Manufacturer address: G.S Pharmbutor Private Limited, B-172, Industrial Area, Behror-301 701, Rajasthan, India.
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: Osmowin
Manufacturing details: batch number, manufacturing date, expiry date
Name of manufacturer: G.S Pharmbutor Private 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.

Mock labels are appended as annex I.

3. Scientific discussion

Quality of Active Pharmaceutical Ingredient(s)

Information on quality of the API was submitted in form of full details.

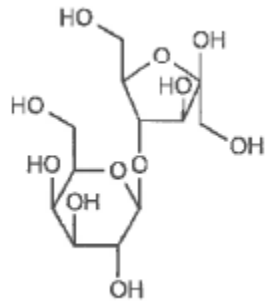
General properties

Lactulose concentrate API is compendia in USP.

Molecular formula: $C_{12}H_{22}O_{11}$

Chemical name: 4-O-d-Galactopyranosyl-D-fructofuranose

Structure:



Critical physico-chemical properties of the API were miscible with water.

Manufacture

The API manufacturing site, Societa Chimica Mugello (S.C.M), Enrico Mattei, 26 Vicchio, Italy,50039 was noted to comply with WHO GMP requirements as evidenced by the GMP certificate issued by <state the issuing authority>. Lactulose concentrate 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: description, identification, related substances, pH, refractive index, residue on ignition, microbial evaluation, tagatose content, colour, density and specific optical rotation.Compliance to these specifications were established via batch analysis data and stability studies.

Stability and container closure system

The re-test period of lactulose concentrate API is 36 months when packed in polyethylene bag and stored at below 25º.

Quality of the Finished Pharmaceutical Product

Formulation

Osmowin is a colourless or pale yellow to amber coloured syrup liquid with sweet taste having lemon flavour. Osmowin contains lactulose concentrate and other ingredients listed here after lemon flavour and purified water.

Manufacture

The finished product was manufactured at G.S Pharmbutor Pvt Ltd, B-172, Industrial Area, Behror-301 701, Rajasthan, India. The compliance of the site to TMDA GMP standards was confirmed through site inspection on 14/09/2020.

Specifications

The FPP is compendia 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, pH, average withdrawable volume, volume variation/minimum fill, related compounds, assay and microbiological 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 30^0C ± 2^0C/75% ± 5% for 24 months and 40^0C ± 2^0C/75% ± 5% for 6 months. Based on the stability data presented, the approved shelf-life is 24 months when stored in amber coloured PET at below 30^0C.

Safety and efficacy information

No studies were required as the formulation is an oral solution.

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. Osmowin 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

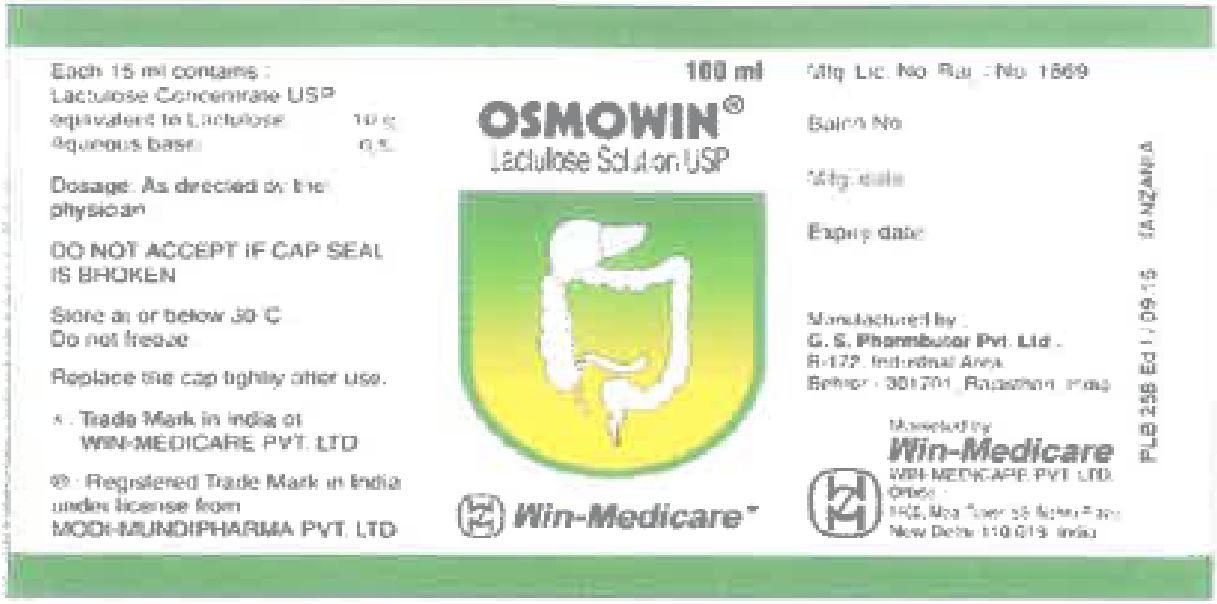
Re-registration applications

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>.

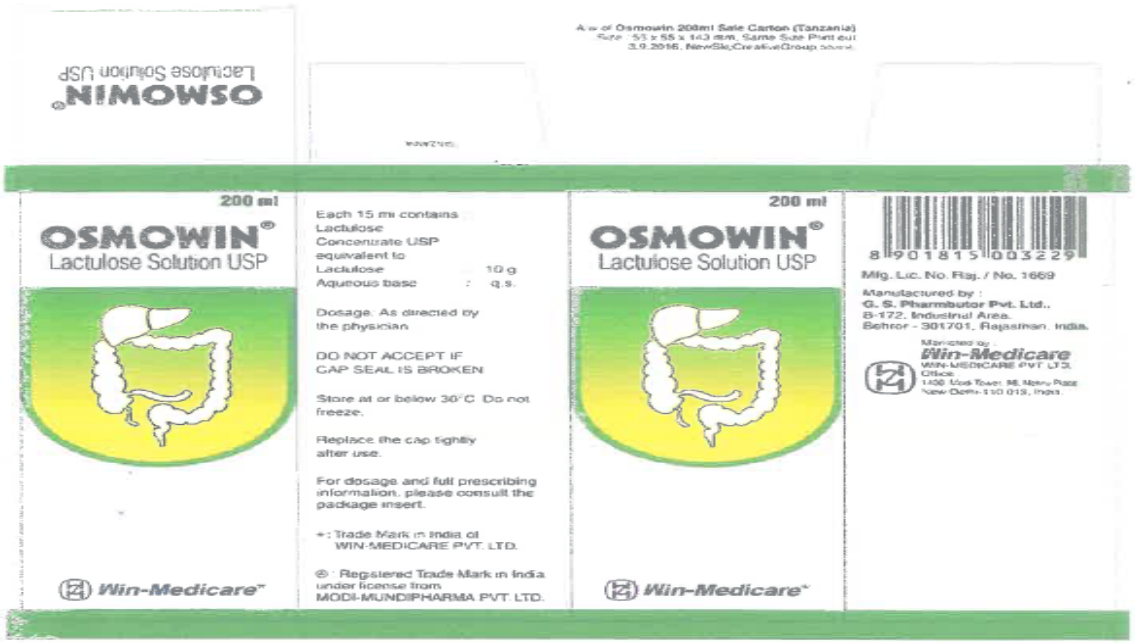
PART 5: CHANGE HISTORY

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

Annex I: Mock up label




A/w of Osmowin 100ml Sale Carton (Tanzania)
Size : 45 x 45 x 115 mm, Same Size Print out
3.9.2016, NewSkyCreativeGroup
100 ml
OSMOWIN®
Lactulose Solution USP
Win-Medicare*
Each 15 ml contains :
Lactulose
Concentrate USP
equivalent to
Lactulose : 10 g
Aqueous base : q.s.
Dosage: As directed by the physician.
DO NOT ACCEPT IF CAP SEAL IS BROKEN
Store at or below 30°C.
Do not freeze.
Replace the cap tightly after use.
For dosage and full prescribing information please consult the package insert.
* : Trade Mark in India of WIN-MEDICARE PVT. LTD.
® : Registered Trade Mark in India under license from MODI-MUNDIPHARMA PVT. LTD.
8 901815 003212
Mfg. Lic. No. Raj. / No. 1669
Manufactured by :
G. S. Pharmbator Pvt. Ltd.,
B-172, Industrial Area,
Behror - 301701, Rajasthan, India
Marketed by
Win-Medicare
WIN-MEDICARE PVT LTD
Office :
TANZANIA


OSMOWIN®
Lactulose Solution USP
200 ml
OSMOWIN®
Lactulose Solution USP
Each 15 ml contains :
Lactulose
Concentrate USP
equivalent to
Lactulose 10 g
Aqueous base : q.s.
Dosage. As directed by the physician
DO NOT ACCEPT IF CAP SEAL IS BROKEN
Store at or below 30°C. Do not freeze.
Replace the cap tightly after use.
For dosage and full prescribing information, please consult the package insert.
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®: Registered Trade Mark in India under license from MODI-MUNDIPHARMA PVT. LTD.
Win-Medicare
200 ml
OSMOWIN®
Lactulose Solution USP
Win-Medicare
8 901815 003229
Mfg. Lic. No. Reg. / No. 1669
Manufactured by :
G. S. Pharmibutor Pvt. Ltd.,
B-172, Industrial Area,
Behror - 301701, Rajasthan, India.
Win-Medicare