THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR MICOR ORAL (MICONAZOLE 2% W/W) GEL

Version number 1.0
21 August 2023

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1. Introduction

Micor oral is a s a generic medicine of Daktarin Sugar Free 2% Oral Gel, McNeil Products Limited. Micor oral contains miconazole which possesses an antifungal activity against the common dermatophytes and yeasts as well as an antibacterial activity against certain gram-positive bacilli and cocci. Its activity is based on the inhibition of the ergosterol biosynthesis in fungi and the change in the composition of the lipid components in the membrane, resulting in fungal cell necrosis. Micor oral is approved in Tanzania for use in adults and pediatric population.

1.1 Product details

Registration number	TAN 21 H 0327
Brand name	Micor oral
Generic name, strength, and form	Miconazole Nitrate 2.0% w/w
ATC classification	ATC Code: A01A B09 and A07A C01
Distribution category	POM
Country of origin	India
Associated product	N/A
Marketing Authorization Holder	Coral Laboratories Ltd, 3B, Pantawala Compound, Opp. Shreyas Cinema, L.B.S. Marg, Ghatkopar (West), Mumbai, 400 086 India.
Local Technical Representative	Moraf Pharmaceutical Ltd, P.O.BOX 21323, Dar Es Salaam.

1.2 Assessment procedure

The application for registration of Micor oral was submitted on 29 June 2020. The product underwent full assessment. Assessment was completed in 3 (three) rounds of evaluation and the product was registered on 01 June 2023.

1.3 Information for users

Visual description of the finished product	A white colour smooth gel
Primary packing material	Aluminium tube
Secondary packing materials	A printed carton box
Shelf-life and storage condition	36 months, Store below 30°C. Protect from light and moisture. Do not freeze.
Route of administration	Oral
Therapeutic indications	Is indicated for the treatment of fungal infections of the mouth (e.g., thrush in babies and oral candidiasis in other age groups) and for fungal stomatitis occurring in association with dentures

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.

Container labels
The product label information is presented in English. Details in the secondary pack label include:
Brand name: Micor oral

Composition: Miconazole Nitrate 2.0% w/w

Pack size: 1 tube

Manufacturing details: batch number, manufacturing date, and expiry date

Storage conditions: Store below 30°C. Protect from light and moisture. Do not freeze.

Manufacturer address: physical address of release site

Unique identifier: Not applicable

Special warnings/precautions or instructions for use: See enclosed leaflet

The details of the primary pack include:

Brand name and strength: Micor oral

Manufacturing details: batch number, manufacturing date and expiry date

Name of manufacturer: Coral Laboratories Ltd

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 appended as annex I.

3. Scientific discussion

Quality of Active Pharmaceutical Ingredient

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

Miconazole Nitrate

General Information

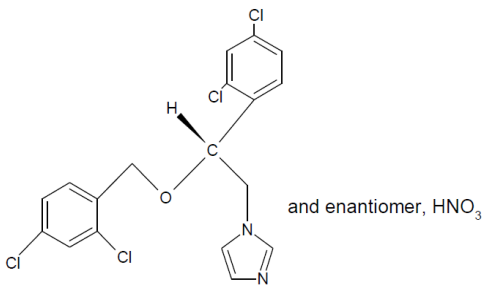
Miconazole Nitrate API is compendia in USP, Ph.Eur., and BP.

Molecular formula: $C_{18}H_{15}Cl_4N_3O_4$

Chemical name:

1-[(2RS)-2-[(2,4-dichlorobenzyl) oxy]-2-(2,4-dichlorophenyl) ethyl]-1H-imidazole Nitrate

Structure:



General properties

The active substance is a white or almost white powder that is practically insoluble in water, soluble in acetone and alcohol. Miconazole exhibit potential for isomerism and polymorphism based on literature reference.

Manufacture

Miconazole Nitrate API manufacturer is Pranami Drugs Pvt Ltd, Plot No. 7209, GIDC Industrial Estate, Ankleshwar – 393002, Bharuch, Gujarat, India. The manufacturing complies with GMP requirements as evidenced by the GMP certificate issued by the Food & Drugs Control Administration, Gujarat, India. Miconazole Nitrate 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 Ph Eur standards and ICHQ3A. The parameters monitored during quality control are: Description, solubility, identification (Melting point, IR Spectrum, TLC, and Nitrate Test), appearance of solution, optical rotation, loss on drying, residue on ignition,

heavy metals, related substances, assay, and residual solvents. Compliance to these specifications were established via batch analysis data and stability studies.

Stability and container closure system

The re-test period of Miconazole Nitrate API is 36 months when packed in double polyethylene bags in fiber drums with storage condition 'Store below 25˚C'.

Quality of the Finished Pharmaceutical Product

Formulation

Micor oral is a white colour smooth gel.

Micor oral contains the Miconazole Nitrate, and other ingredients listed here after: carbomer 934, sodium saccharin, glycerin, sodium benzoate, sodium methyl hydroxybenzoate, sodium propyl hydroxybenzoate, citric acid monohydrate, sorbitol solution 70%, triethanolamine, flavor sweet orange no.1, flavor peppermint 18774, purified water. The quantities of all ingredients are confirmed to be in line with the recommendations of Handbook of Pharmaceutical Excipients, 8th Edition in terms of function and quantities.

Manufacture

The finished product manufacturers are CORAL Laboratories Ltd, Plot No. 27/28, Pharmacity, Selaqui, Dehradun, and Uttarakhand, India. The compliance of the sites to TMDA GMP standards was confirmed through site inspection on 24 August, 2019.

Specifications

The FPP is compendia. The manufacturer controls the quality of the finished product as per BP and ICH requirements. The parameters monitored during quality control are: visual description, identification of API (UV and HPLC), assay, related substances (HPLC), pH, uniformity of weight, and microbiological quality. Compliance to the standard was established using batch analysis data and stability data.

Stability and container closure system

Stability studies were conducted on three (3) batches of the finished product stored at 30 ± 2°C & RH: 75 ± 5% RH for 36months 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 aluminium tube with storage condition 'Store below 30°C. Protect from light and moisture. Do not freeze'.

Safety and efficacy information

API used in this product is a well-known active substance with established efficacy and tolerability. A clinical overview has been provided, which is based on scientific literature. The overview justifies why there is no need to generate additional clinical data. Therefore, the member states agreed that no further clinical studies are required.

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. Micor oral 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

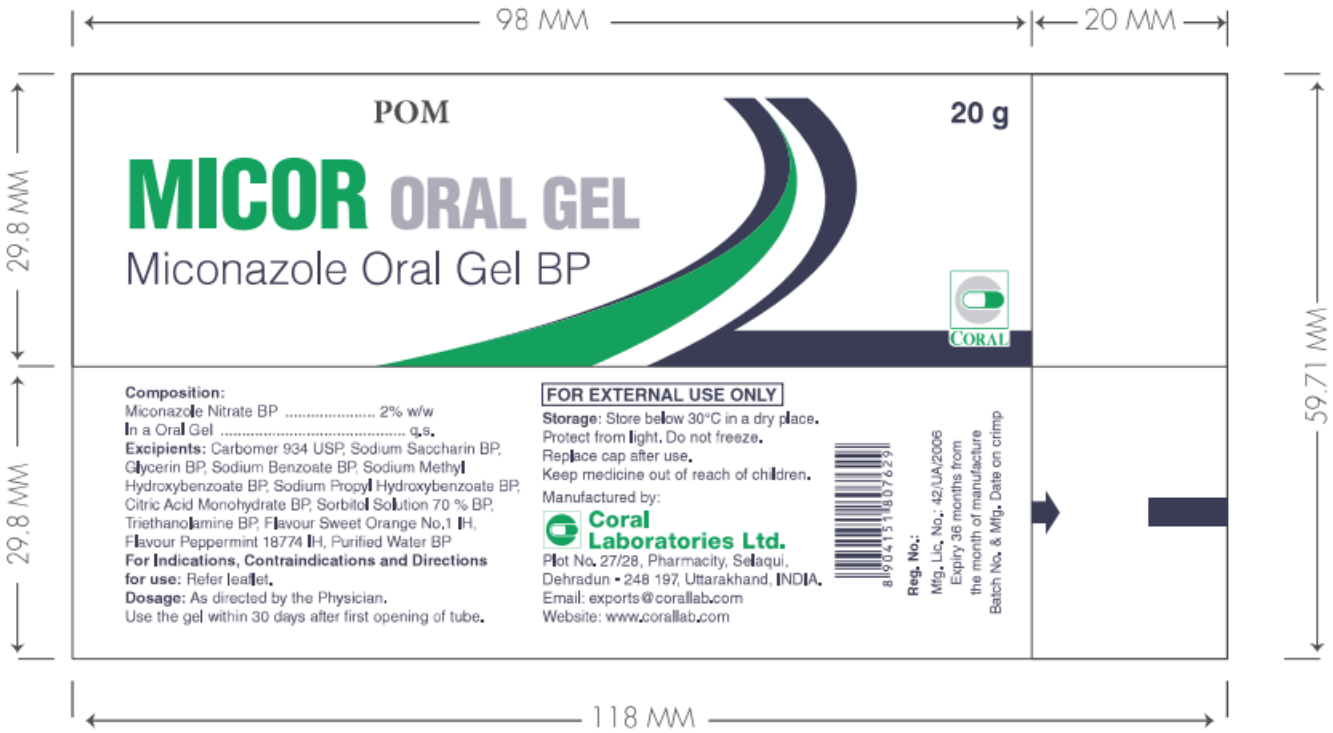
Application for renewal of registration was submitted on <DDMMYYYY>. The application was finalized in <number> rounds of evaluation. The product was confirmed to still be compliant to the standards of quality, safety and efficacy, hence registration was renewed on <DDMMYYYY>.

PART 5: CHANGE HISTORY

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

Annex I: Mock up labels;

Primary pack label;



Secondary pack label;

Effective date: 03/10/2022