

Summary of Product Characteristics

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1. NAME OF THE MEDICINAL PRODUCT

Micomed (Miconazole Nitrate Cream BP 2%)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gm contains:

Miconazole Nitrate BP 2% w/w

In a cream base q.s.

For the list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Semi Solid Dosage Form

White homogeneous cream.

CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of mycotic infections of the skin and nails and superinfections due to Gram-positive bacteria.

4.2 Posology and Method of administration

Route of administration: Cutaneous use.

Recommended dosage:

For all ages:

Fungal infections of the skin: Apply some cream to the lesions two times daily. Rub the cream into the skin with your finger until it has fully penetrated. If the powder is used with the cream, a once daily application of both formulations is recommended. The duration of therapy varies from 2 to 6 weeks depending on the localisation and the severity of the lesion. Treatment should be continued at least one week after disappearance of all signs and symptoms.

Nail infections: Apply the cream once or twice daily to the lesions. Treatment should be prolonged for 10 days after all lesions have disappeared to prevent relapse.

4.3 Contraindications

Hypersensitivity to the active substance, other imidazole derivatives or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Cream must not come into contact with the mucosa of the eyes.

Severe hypersensitivity reactions, including anaphylaxis and angioedema, have been reported during treatment with Miconazole Cream and with other miconazole topical formulations (see Adverse Reactions). If a reaction suggesting hypersensitivity or irritation should occur, the treatment should be discontinued.

This medicine contains 2 mg of Benzoic acid (E210) per gram. Benzoic acid may cause local irritation. Benzoic acid may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

This medicine also contains 0.052 mg/g of Butylated hydroxyanisole (E320) which may cause local skin reactions (e.g., contact dermatitis), or irritation to the eyes and mucous membranes.

4.5 Interaction with other medicinal products and other forms of interact.

Miconazole administered systemically is known to inhibit CYP3A4/2C9. Due to the limited systemic availability after topical application, clinically relevant interactions are rare. However, in patients on oral anticoagulants, such as warfarin, caution should be exercised and anticoagulant effect should be monitored.

4.6 Fertility, Pregnancy and Lactation

Pregnancy

In animals miconazole nitrate has shown no teratogenic effects but is foetotoxic at high oral doses. Only small amounts of miconazole nitrate are absorbed following topical administration. However, as with other imidazoles, miconazole nitrate should be used with caution during pregnancy.

Breast-feeding

Topically applied miconazole is minimally absorbed into the systemic circulation, and it is not known whether miconazole is excreted in human breast milk. Caution should be exercised when using topically applied miconazole products during lactation.

4.7 Effects on ability to drive and use machines

This Cream has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse drug reactions reported among 834 patients who received miconazole nitrate 2% cream (n=426) and/or placebo cream base (n=408) in 21 double-blind clinical trials are presented in Table 1 below. Moreover, adverse drug reactions from spontaneous reports

during the worldwide post-marketing experience with Miconazole that meet threshold criteria are included in Table 1. The adverse drug reactions are ranked by frequency, using the following convention:

Very common $\geq 1/10$

Common $\geq 1/100$ and $< 1/10$

Uncommon $\geq 1/1,000$ and $< 1/100$

Rare $\geq 1/10,000$ and $< 1/1,000$

Very rare $< 1/10,000$, including isolated reports

Adverse reactions obtained from clinical studies and post-marketing surveillance are presented by frequency category based on incidence in clinical trials or epidemiology studies, when known.

Table 1: Adverse reactions reported in clinical trials and post-marketing experience

System Organ Class	Adverse Reactions	
	Frequency Category	
	Uncommon ($\geq 1/1,000$ to $< 1/100$)	Not known
Immune System Disorders		Anaphylactic reaction Hypersensitivity
Skin and Subcutaneous Tissue Disorders	Skin burning sensation Skin inflammation Skin hypopigmentation	Angioedema Urticaria Contact dermatitis Rash Erythema Pruritus
General Disorders and Administration Site Conditions	Application site irritation Application site burning Application site pruritus Application site reaction NOS Application site warmth	

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

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Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via EFDA yellow Card Scheme, online at <https://primaryreporting.who-umc.org/ET> or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

Symptoms

Cutaneous use: Excessive use can result in skin irritation, which usually disappears after discontinuation of therapy.

Treatment

Miconazole cream is intended for cutaneous use, not for oral use. If accidental ingestion of large quantities of the product occurs, use appropriate supportive care.

5.0 Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic classification: (Antifungals for dermatological/topical use; imidazole derivative)

ATC code: D01A C02.

Miconazole nitrate is an imidazole antifungal agent and may act by interfering with the permeability of the fungal cell membrane. It possesses a wide antifungal spectrum and has some antibacterial activity.

5.2 Pharmacokinetic properties

Absorption: There is little absorption through skin or mucous membranes when miconazole nitrate is applied topically.

Distribution: Absorbed miconazole is bound to plasma proteins (88.2%) and red blood cells (10.6%).

Metabolism and Excretion: The small amount of miconazole that is absorbed is eliminated predominantly in faeces as both unchanged drug and metabolites.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of local irritation, single and repeated dose toxicity, genotoxicity, and toxicity to reproduction.

6.0 Pharmaceutical particulars

6.1 List of excipients

Cetostearyl Alcohol, Cetomacrogol, Light liquid Paraffin, P-Chlorocresol, Propylene Glycol, Butylated Hydroxy Anisole, White Petrolatum Jelly

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Do not store above 30°C. Do not refrigerate.

6.5 Nature and contents of container

30 gm cream packed in a printed Lami Tube in a unit carton along with the package Insert.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7.0 Marketing Authorisation Holder

MEDICAMEN BIOTECH LIMITED

Plot No. 86-87, Sector-6A, IIE, SIDCUL,

Ranipur, Haridwar – 249403

Uttarakhand (India)

8.0 Number(s) in the national register of finished pharmaceutical products

Certificate No: 08265/09892/NMR/2022

9.0 Date of first authorisation/renewal of the authorisation

Dec 26, 2022

10.0 Date of revision of the text

July 2023