DACINAZOLE®
(MICONAZOLE CREAM)

Description: A white non- gritty Cream.
Composition: Contains Miconazole Nitrate BP 2%w/w
Pharmacology: Miconazole is an imidazole antifungal which interferes with ergosterol synthesis and therefore alters the permeability of the cell membrane of sensitive fungi. It is reported to be fungistatic at concentrations achieved clinically. Miconazole has a wide spectrum of antimicrobial activity including activity against Blastomyces dermatitidis, Candida spp., Coccidioides immitis, Epidermophyton floccosum, Histoplasma capsulatum, Malassezia spp., Microsporum canis, Paracoccidioides brasiliensis, Trichophyton mentagrophytes, and T. rubrum. Some strains of Aspergillus spp., Cryptococcus neoformans, and Sporothrix schenckii are sensitive. It also has some activity against *Aspergillus* spp., Cryptococcus neoformans, Pseudallescheria boydii, and some Gram-positive bacteria including staphylococci and streptococci
Pharmacokinetics: There is little absorption through skin or mucous membranes when miconazole nitrate is applied topically. Absorbed miconazole is bound to plasma proteins and red blood cells. Miconazole is metabolised in the liver to inactive metabolites. The small amount of miconazole that is absorbed is eliminated predominantly in faeces as both unchanged drug and metabolites.
Indications: Miconazole is an imidazole antifungal used in the treatment **of superficial candidiasis** and of the skin infections dermatophytosis and pityriasis versicolor. For topical application in the treatment of tinea pedis (athlete's foot), tinea cruris, and tinea corporis caused by *Trichophyton rubrum*, *Trichophyton mentagrophytes*, and *Epidermophyton floccosum*, in the treatment of cutaneous candidiasis (moniliasis), and in the treatment of tinea versicolor.
Dosage and directions for use
For external use only.
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. The duration of therapy varies from 2 to 6 weeks depending on the localization 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.
Contraindications: Dacinazole cream is contraindicated in individuals with a known hypersensitivity to miconazole/miconazole nitrate, other imidazole derivatives or to any of the excipients.
Special warnings and precautions for use: Severe hypersensitivity reactions, including anaphylaxis and angioedema, have been reported during treatment with Miconazole topical formulations. If a reaction suggesting hypersensitivity or irritation should occur, the treatment should be discontinued. Miconazole cream must not come into contact with the mucosa of the eyes.
Interaction with other medicinal products and other forms of interaction: 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.
Pregnancy and lactation: 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.
Lactation: 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.
Effects on ability to drive and use machines: Not applicable
Undesirable effects: The most common adverse effects includes skin burning sensation, skin inflammation and application site reactions which includes application site irritation, burning, pruritus, reaction NOS and warmth.
Overdose: Excessive use can result in skin irritation, which usually disappears after discontinuation of therapy. Accidental ingestion cause stomach irritation.
Management of overdose: 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.
Presentation: Collapsible tube of 15gram
Storage: Store in dry place below 30°C. Protected from light. Keep all medicines out of reach of children.
Shelf life: 3year from the date of manufacture.
Manufactured By:

DAWA Limited, Plot No. 7879/8, Baba Dogo Road, Ruaraka
P. O. Box 16633 – 00620, Nairobi, Kenya.

Ref: DAC/LL/08/19 Date of issue: August 2019