Summary product characteristics

1. Name of the medicinal product
Dacinazole cream.

2. Qualitative and quantitative composition
Miconazole nitrate BP 2% w/w.
(Each gram of cream contains 20mg of Miconazole nitrate)
For the full list of excipients, see Section 6.1

3. Pharmaceutical form
Cream
White coloured, non- gritty cream free from visible evidence of contamination.

4. 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
Dacinazole cream is contraindicated in individuals with a known hypersensitivity to Miconazole nitrate, other imidazole derivatives or to any of the excipients

4.4 Special warnings and precautions for use
Severe hypersensitivity reactions, including anaphylaxis and angioedema, have been reported during treatment with Dacinazole cream and with other Miconazole topical formulations .
If a reaction suggesting hypersensitivity or irritation should occur, the treatment should be discontinued. Dacinazole cream must not come into contact with the mucosa of the eyes.
This medicine contains Benzoic acid may cause local irritation and may increase jaundice in new-born babies (up to 4 weeks old).

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

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.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Adverse reactions reported among 426 patients who received miconazole 2% cream base in 21 double-blind clinical trials are presented in Table A below.

Based on pooled safety data from these clinical trials, the most commonly reported adverse reaction was Application site irritation (0.7%).

Including the above-mentioned adverse reaction, Table A displays adverse reactions that have been reported with the use of topical, non-gynaecological, miconazole nitrate/miconazole from either clinical trial or postmarketing experiences.

The displayed frequency categories use the following convention: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); and very rare (< 1/10,000, including isolated reports) and Not Known (cannot be estimated from the available data).

Table A: Adverse Reactions Reported in Clinical Trials and Post-marketing Experience

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

4.9 Overdose

Symptoms

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

Accidental ingestion: Stomach irritation may occur.

Treatment Dacinazole 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. 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
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. Pharmaceutical particulars
6.1 List of excipients
Liquid paraffin
White soft paraffin
Cetostearyl Alcohol
Cetomacrogol 1000
Propylene glycol
Benzyl alcohol
Sodium Acid Phosphate
Purified water

6.2 Incompatibilities
None known.

6.3 Shelf life
3 years.

6.4 Special precautions for storage
Store below 30°C. Store in the original carton in order to protect from light.

6.5 Nature and contents of container
15gm cream packed in collapsible aluminium tubes in a unit carton with a literature insert

6.6 Special precautions for disposal and other handling
No special instructions

7. Manufacturer
Dawa limited,
Plot No: 7879/8, Baba Dogo road, Ruaraka,
P.O Box 16633-00620, Nairobi –Kenya.

8. Marketing authorization holder.
Dawa limited,
Plot No: 7879/8, Baba Dogo road, Ruaraka,
P.O Box 16633-00620, Nairobi –Kenya.

9. Legal category: Prescription only medicine, (POM)

10. Date of revision of the text.
May 2020.