SUMMARY OF PRODUCT CHARACTERISTICS

DERMIDEX CREAM

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1. Name of the medicinal product

Dermidex Cream.

2. Qualitative and quantitative composition

Miconazole nitrate 2% w/w.

For a full list of excipients, see Section 6.1.

3. Pharmaceutical form

Cream

Smooth white cream, free from visible impurities.

4. Clinical particulars

4.1 Therapeutic indications
Dermidex is indicated for the treatment of fungal infections of the skin and super infections due to gram-positive bacteria.These include athlete's foot, ringworm (tinea infections), intertrigo, candida nappy rash, paronychia, erythrasma, fungal infections of the outer ear and pityriasis versicolor. It may also be used for nail infections

4.2 Posology and method of administration
Route of administration: Topical

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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 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.

4.3 Contraindications
Hypersensitivity to the active substances(s), other imidazole derivatives or to any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use
Dermidex 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 Dermidex Cream and with other Miconazole topical formulations (see Adverse Reactions). If a reaction suggesting hypersensitivity or irritation should occur, the treatment should be discontinued.

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

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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
Not relevant.

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 Dermidex that meet threshold criteria

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 (≥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	

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4.9 Overdose
Symptoms

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

Treatment

Dermidex 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.

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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. Pharmaceutical particulars

6.1 List of excipients
Chlorocresol

Cetomacrogol

Emulsifying wax

Liquid Paraffin

Propylene Glycol

Polysorbate 80 (Tween-80)

Disodium Hydrogen Phosphate Dodecahydrate

White Soft Paraffin

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6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Do not store above 25°C.

6.5 Nature and contents of container
Dermidex Cream tubes. Unit cartons, leaflets, outer carton labels. B.O.P.P. Tape white coloured, printed 'REGAL PHARMACEUTICALS LTD, P. O. Box 44421, Nairobi. & Logo in light Blue Colour**6.6 Special precautions for disposal and other handling**
No special requirements.

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

7. Marketing authorization holder

Company) Name: REGAL PHARMACEUTICALS LTD

Address: P.O BOX 44410-00100 GPO, NAIROBI

Country: KENYA

Telephone: 8564211/2/3/4

Telefax: 8560946/8564093

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E-Mail: info@regalpharmaceuticals.com

8. Marketing authorization number(s)

KENYA- H2005/412

UGANDA- NDA/MAL/HDP/2368

TANZANIA- TAN 06, 205 D01A REG

9. Date of first authorization/renewal of the authorization

01/01/2006

10. Date of revision of the text

13 November 2018

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DECLARATION BY AN APPLICANT

I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge.

I further confirm that the information referred to in my application dossier is available for verification during GMP inspection.

I also agree that I shall carry out pharmacovigilance to monitor the safety of the product in the market and provide safety update reports to the National Medicines Regulatory Authority of the EAC Partners States.

I further agree that I am obliged to follow the requirements of the Partner States Legislations and Regulations, which are applicable to medicinal products.

I also consent to the processing of information provided by the EAC Partner States.

It is hereby confirmed that fees will be paid/have been paid according to the National/Community rules*

Name: DR. MANDERE ATEBE JAMES
Position in the company: COMPANY PHARMACIST

Signature: .....

Date: 10 May 2019.

Official stamp:.....

* Note: If fees have been paid, attach proof of payment