Summary product characteristics:

1.0 Name of the product:
Kenazole Cream

2.0 Qualitative and quantitative composition:
Ketoconazole 2% w/w
Full list of excipients see section 6.1.

3.0 Pharmaceutical form:
Topical cream
White coloured, homogeneous cream, non- gritty and non-greasy on application to the skin, free from visible evidence of contamination

4.0 Clinical particulars:
4.1Therapeutic indications:
Kenazole Cream is indicated for topical application in the treatment of dermatophyte infections of the skin such as tinea corporis, tinea cruris, tinea manus and tinea pedis infections due to Trichophyton spp, Microsporon spp and Epidermophyton spp. It is also indicated for the treatment of cutaneous candidosis (including vulvitis), tinea (pityriasis) versicolor and seborrhoeic dermatitis caused by Malassezia (previously called Pityrosporum) spp.

4.2 Posology and method of administration:
Route of administration: For Topical application.
Dosage:It is applied once or twice daily and continued for at least a few days after the disappearance of symptoms.

4.3 Contraindications:
Kenazole 2%w/w cream is contra-indicated in patients with a known hypersensitivity to ketoconazole or any excipients

4.4 Special warnings and precautions for use:
Kenazole 2%w/w cream is not for ophthalmic use.
To prevent a rebound effect after stopping a prolonged treatment with topical corticosteroids it is recommended to continue applying a mild topical corticosteroid in the morning and to apply Kenazole 2% cream in the evening, and to subsequently and gradually withdraw the steroid therapy over a period of 2-3 weeks.

4.5 Interaction with other medicinal products and other forms of interaction:
No interactions with other drugs have been described for topical ketoconazole.

4.6 Pregnancy and Lactation
There are no adequate and well-controlled studies in pregnant or lactating women. Data on a limited number of exposed pregnancies indicate no adverse effects of topical ketoconazole on pregnancy or on the health of the foetus/newborn child. Plasma concentrations of ketoconazole are not detectable after topical application of Ketoconazole 2% Cream to the skin of non-pregnant humans. There are no known risks associated with the use of ketoconazole 2% Cream in pregnancy or lactation.

4.7 Effects on ability to drive and use machines:
No influence on the ability to drive or operate machinery

4.8 Undesirable effects:
After topical administration of ketoconazole, irritation, dermatitis, or a burning sensation has occurred.

4.9 Overdose:
Excessive topical application may lead to erythema, oedema and a burning sensation, which will disappear upon discontinuation of the treatment.
Ingestion In the event of accidental ingestion, supportive and symptomatic measures should be carried out.

5.0 Pharmacological properties:
5.1 Pharmacodynamic properties:
Pharmacotherapeutic group: Antifungal agent.
ATC Code: D01AC08
Ketoconazole, a synthetic imidazole dioxolane derivative 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. Ketoconazole, a synthetic imidazole dioxolane derivative, has a potent antimycotic activity against dermatophytes such as Trichophyton spp., Epidermophyton floccosum and Microsporum spp. and against yeasts, including Malassezia spp. and Candida spp. The effect on Malassezia spp. is particularly pronounced.

5.2 Pharmacokinetic properties:
Plasma concentrations of ketoconazole were not detectable after topical administration of Ketoconazole 2% w/w
Ketoconazole is rarely absorbed from the skin after topical application; quantities absorbed in inflamed skin are also of no pharmacokinetic significance.

5.3 Preclinical safety data:
There are no preclinical data of relevance additional to that already included in other sections of the summary product characteristics.

6.0 Pharmaceutical particulars:
6.1 List of excipients:
White soft paraffin,
Liquid 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 in a dry place ,below 30^{o}C protected from light.
Keep out of reach of children.

6.5 Nature and contents of the container:
20gm cream packed in collapsible aluminium tubes in a unit carton.

7.0 Manufacturer:
Dawa Limited,
Plot No. 7879/8, Baba Dogo Road, Ruaraka,
P.O. Box 16633 – 00620,
Nairobi, Kenya.
Email: admin@dawalimited.com

8.0 Marketing authorisation holder
Dawa Limited,
Plot No. 7879/8, Baba Dogo Road, Ruaraka,
P.O. Box 16633 – 00620,
Nairobi, Kenya.
Email: admin@dawalimited.com

9.0 Marketing authorization number(s)
Kenya, license No. H2013/CTD776/109

10 Legal category: Prescription only medicine, (POM)

11. Date of revision of the text
June 2018