Summary of product characteristics.

1. Name of the medicinal product.
Miclocin cream.

2. Qualitative and quantitative composition
Contains: Miconazole Nitrate BP 2% w/w, Clobetasol Propionate BP0.05% w/w Gentamicin (as Sulphate) BP0.1% w/w
For more information on excipients see section 6.1

3. Pharmaceutical form
Topical cream
White coloured homogenous cream, non-gritty and non-greasy on application to the skin.

4. Clinical particulars
4.1 Therapeutic indications
Miclocin cream is indicated for topical application in the treatment of chronic dermatitis of
extremetis, eczematous dermatitis, pustular acne, pustular psoriasis, infected seborrheic dermatitis, infected excoriations, and bacterial super infections of fungal or viral infections.
Miclocin cream is also used in the treatment of follicular dermatitis, invertrigo, tinea pedis (athlete's foot)/cruris/corporis, relieves itching, burning, cracking, or scaling of the feet and photosensitive dermatitis. It is also used in the treatment of infected stasis and other skin ulcers, infected superficial burns, paronychia, infected insect bites and stings, infected lacerations and abrasions, and wounds from minor surgery.

4.2 Posology and method of administration
Route of administration: Topical application
Apply a thin layer of MICLOCIN Cream to the affected skin areas twice daily. Treatment should not be more than 14 consecutive days and not more than 50g per week should not be used. It should be discontinued when control has been achieved. If no improvement is seen within 2 weeks, reassessment of diagnosis may be necessary. MICLOCIN Cream should not be used with occlusive dressings.

4.3 Contra-indications.
The preparation is contraindicated in patients with a history of hypersensitivity to any of the components of the preparation.
Topical application of gentamicin into the ear is contra-indicated in patients with known or suspected perforation of the ear drum.
Miclocin Cream is for external use only. It should not be taken by or used inside the mouth. Avoid contact with the eyes.

4.4 Special warning and precautions for use.
•Miclocin cream should not be used in those patients with a history of hypersensitivity to any of the components of this preparation.
•Do not use on the scalp or nails.
•Wash hands after applying.

4.5 Interaction with other medicinal products and other forms of interaction.
Co-administered drugs that can inhibit CYP3A4 (e.g. Ritonavir and itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure. The extent to which this interaction is clinically relevant depends on the dose and route of administration of the corticosteroids and the potency of the CYP3A4 inhibitor.
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.
The interaction is relevant for all routes of administration; however, it is more relevant to routes of administration that generate the highest systemic exposure.

4.6 Pregnancy and lactation.
Miclocin Cream should not be used during pregnancy or lactation.

4.7 Effects on ability to drive and use machines.
Miclocin cream has no influence on the ability to drive or operate machinery

4.8 Undesirable effects.
Rare side effects include: thinning of the skin; appearance of fine blood vessels on the skin surface; infections of hair follicles; excessive unwanted hair growth; redness and irritation around the mouth (peri-oral dermatitis; allergic skin reactions).

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. Pharmacological properties.
5.1 Pharmacodynamic properties.
Pharmacotherapeutic group: Antifungal, antibacterial & anti-inflammatory agent for topical application.
ATC Code: D07 ADOl
Clobetasol propionate is a highly active corticosteroid with topical anti-inflammatory activity. The major effect of Clobetasol propionate on skin is a non-specific anti-inflammatory response, partially due to vasoconstriction and decrease in collagen synthesis.
Miconazole nitrate is a synthetic anti fungal agent which inhibits the growth of the common dermatophytes, Trichophyton rubrum, Trichophyton mentagrophytes, Epidermophyton floccosum, Candida albicans and the organism responsible for the tinea versicolor(.Malassezia
furfur).Miconazole damages fungal organisms by interfering with ergosterol biosynthesis,which results in toxic methylated sterol levels.
Gentamycin is an aminoglycoside antibiotic and has a bactericidal action against many Gram-negative aero bes and against some strains of staphylococci. Gentamycin is taken up into sensitive bacterial cells by an active transport process which is inhibited in anaerobic, acidic, or hyperosmolar environments. Within the cell they bind to the 30S and to some extent to the SOS, subunits of the bacterial ribosome, inhibiting protein synthesis and generating errors in the transcription of the genetic code. The manner in which cell death is brought about is imperfectly understood, and other mechanisms may contribute, including effects on membrane permeability.

5.2 Pharmacokinetic properties:
Systemic absorption of miconazole is limited, with a bioavailability of less than 1 % following application of miconazole. Plasma concentrations of miconazole and/or its metabolites were measurable 24 and 48 hours after application. Absorbed miconazole is bound to plasma proteins
(88.2%) and red blood cells (10.6%). The small amount of miconazole that is absorbed is eliminated predominantly in feces as both unchanged drug and metabolites over a four-day post-administration period. Smaller amounts of unchanged drug and metabolites also appear in urine. Gentamicin is absorbed in insignificant amounts through intact skin; absorption through damaged skin is up to 5%. As is the case with other aminoglycosides, gentamicin poorly binds to plasma proteins and is excreted almost entirely by glomerular filtration. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Clobetasol propionate can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption. Greater absorption is observed for the Clobetasol propionate gel formulation as compared to the cream formulation in vitro human skin penetration studies.

5.3 Preclinical safety data.
No additional data of relevance.

6. 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.
36 months from the date of manufacture.

6.4 Special precautions for storage:
Store in cool dry place below 30°C ,Protect from light
Keep all medicines out of reach of children.

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

6.6 Special precautions for disposal and other handling
No special requirements.

7. Marketing authorization holder
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
March 2020.