SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

NAXACIN

Betamethasone Dipropionate, Salicylic Acid, Urea & Lactic Acid Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:

Betamethasone Dipropionate USP	0.05 % w/w
Salicylic Acid USP	3 % w/w
Urea USP	10 % w/w
Lactic Acid USP	3 % w/w
Sodium Lactate Solution USP	
Eq. to Lactic Acid	2 % w/w
Ointment Base	q.s.

Betamethasone Dipropionate USP.....0.05 % w/w

Salicylic Acid USP..... 3 % w/w

Urea USP.....10 % w/w

Lactic Acid USP.....3 % w/w

Sodium Lactate Solution USP

Equivalent to Lactic Acid.....2 % w/w

Ointment Base q.s.

3. PHARMACEUTICAL FORM

Ointment

Off White colour, thick, soft mass, filled in lami tubes.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This is a combination of four medicines: Betamethasone, Lactic Acid, Salicylic Acid and Urea which treat eczema and psoriasis. Betamethasone is a steroid which blocks the production of certain chemical messengers (prostaglandins) that make the skin red, swollen and itchy. Lactic Acid, Salicylic Acid and Urea are keratolytic medicines which break down keratin clumps, remove dead skin cells and soften the skin. They also enhance the absorption of Betamethasone into the skin, which treats eczema and psoriasis.

4.2 Dosage and Administration

Once to twice daily. In most cases a thin film of Ointment should be applied to cover the affected area twice daily. For some patients adequate maintenance therapy may be achieved with less frequent application.

If your condition does not improve after a 3-4-week treatment, your doctor will decide whether you should continue the therapy with this product.

4.3 Contraindications

Rosacea, acne, perioral dermatitis, perianal and genital pruritus. Hypersensitivity to any of the ingredients of the Betamethasone Dipropionate, Salicylic Acid, Urea & Lactic Acid Ointment presentations contra-indicates their use, as does tuberculous and most viral lesions of the skin, particularly herpes simplex, vaccinia, varicella. Betamethasone Dipropionate, Salicylic Acid, Urea & Lactic Acid Ointment should not be used in napkin eruptions, fungal or bacterial skin infections without suitable concomitant anti-infective therapy.

4.4 Special Warnings and Precautions for use

Talk to your doctor, pharmacist or nurse before using NAXACIN. You should be aware that the long-term administration of:

- Highly active corticosteroids may result in thinning of the skin and widening of the superficial blood vessels in the treated areas, especially when the product is applied on the skin of the face;
- Topical corticosteroids, high-dose use or treatment of large skin areas may result in significant corticosteroid penetration through the skin to the blood and inhibition of the adrenal activity. These manifestations are more common in young children. Hypercorticoidism (see “Possible side effects”), growth retardation, delayed weight gain and elevated pressure in the skull may develop.
- Avoid contact with the eyes, eyelids, lips and other mucous surfaces. Upon accidental contact, rinse the affected area with clean water.

NAXACIN may cause stinging if applied to damaged skin (raw or cracked areas) or sensitive areas of the body such as the mouth or nostrils.

If you have ever had kidney disease, ask your doctor or pharmacist for advice before taking this medicine.

4.5 Drug Interactions

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. There are no data of unfavourable interactions with other medicines.

4.6 Fertility, Pregnancy and Lactation

There are no adequate and well controlled studies of the teratogenic potential of topically applied corticosteroids in pregnant women. Therefore topical steroids should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

It is not known whether topical administration of corticosteroids would result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, a decision should be made whether to discontinue the drug, taking into account the importance of the drug to the mother.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- Do not apply NAXACIN Cream to your chest if you are breast-feeding.

4.7 Effects on ability to drive and use machines

Betamethasone Dipropionate, Salicylic Acid, Urea & Lactic Acid Ointment has no influence on the performance of activities requiring close attention, such as driving or using machines.

4.8 Undesirable Effects

This medicine can cause side effects, although not everybody gets them. During treatment with the product, the following side effects are likely to occur:

Immune system disorders: Redness, itching, irritation, rashes, inflammation of the skin.

Endocrine system disorders: Rarely, hypercorticoidism (increased production of adrenal hormones) may develop, presented with moon face, obesity in the breast and abdominal areas, reddish-violet skin striae, vulnerability of the blood vessels, muscle weakness.

In some cases: development of diabetes, elevated blood pressure, increased bone fragility (osteoporosis), disturbances in menstruation, excessive bodily terminal hair (hirsutism), acne.

Vascular disorders: Dilatation of the superficial blood vessels in the skin.

Skin and subcutaneous tissue disorders: Sensation of burning and itching at the site of administration.

In rarer cases, thinning of the skin, formation of striae, especially when using occlusive dressings and applying the medicine in areas of skin folds, discolouration (hypo- or hyper-pigmentation) of the skin, excessive bodily terminal hair (hirsutism), skin inflammation, paleness, humidification and

softening of the skin, worsening of psoriasis; added infections are likely to occur.

If you get any side effects, talk to your doctor, pharmacist or nurse.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org '

4.9 Overdose

Excessive prolonged use of topical corticosteroids can suppress pituitary-adrenal functions resulting in secondary adrenal insufficiency which is usually reversible. In such cases appropriate symptomatic treatment is indicated. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, reduce the frequency of application, or to substitute a less potent steroid.

The steroid content of each tube is so low as to have little or no toxic effect in the unlikely event of accidental oral ingestion.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Betamethasone Dipropionate contains the dipropionate ester of betamethasone, which is a glucocorticoid exhibiting the general properties of corticosteroids.

In pharmacological doses, corticosteroids are used primarily for their anti-inflammatory and/or immune suppressive effects.

Topical corticosteroids such as betamethasone dipropionate are effective in the treatment of a range of dermatoses because of their anti-inflammatory, anti-pruritic and vasoconstrictive actions. However, while the physiologic, pharmacologic and clinical effects of the corticosteroids are well known, the exact mechanisms of their action in each disease are uncertain.

Salicylic acid is keratolytic, producing desquamation by solubilising the intercellular cement in the stratum corneum, resulting in the shedding of skin scales.

Lactic acid affects the keratinisation process, reducing the hyperkeratosis which is characteristic of warts. At high concentrations it can cause epidermolysis, leading to the destruction of the keratotic tissue of the wart and of the causative virus. It also has antiseptic properties.

Urea at a concentration of 10% has keratolytic, anti-microbial, anti-pruritic and hydrating effects on the skin.

5.2 Pharmacokinetic properties

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including vehicle, integrity of the epidermal barrier and the use of occlusive dressings.

Topical corticosteroids can be absorbed through intact, normal skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids.

Once absorbed through the skin, topical corticosteroids enter pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees, are metabolised primarily in the liver and excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted in the bile.

Absorption

Salicylic acid is absorbed through the skin; where detectable, maximum plasma levels are found 6 to 12 hours after application. Systemic absorption of salicylic acid has been reported to range from 9% to 25% after topical application of other salicylic acid-containing preparations. The extent of absorption is variable depending on the duration of contact and the vehicle. Despite percutaneous absorption, the systemic exposure is low given the low dose topically administered to small, localised areas of hyperkeratotic tissue.

Human abdominal skin in a flow-through diffusion system was used to assess the in vitro percutaneous absorption of lactic acid. At a pH of 3, the amount of radioactivity detected in the receptor fluid, stratum corneum, epidermis, and dermis was 3.6, 6.3, 6.6, and 13.9%, respectively.

Distribution

Following percutaneous absorption, salicylic acid is distributed in the extracellular space; approximately half of which is protein bound to albumin.

Metabolism

Salicylates are metabolised in the liver by microsomal enzymes to salicyluric acid and phenolic glucuronides of salicylic acid. That which is not metabolised is excreted in the urine as unchanged salicylic acid.

Elimination

Within 24 hours of salicylic acid being absorbed and distributed in the intercellular space, approximately 95% of the absorbed dose can be recovered in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- PEG-400 (Liquid)
- PEG-4000
- Glycerin
- Methyl Paraben
- Propyl Paraben
- White Soft Paraffin

6.2 Incompatibilities

None.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store in a dry and dark place at a temperature below 30°C.

6.5 Nature and contents of container

20 g Lami Tube packed in a carton along with insert.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

H2021/CTD4894/2020ER

9. Date of first authorization/renewal of the authorization

2026 December 01

10. Date of revision of the text

2026 December 01