SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT:

1.1 Brand Name	:	**Beclomin Duo Ointment**
1.2 Generic Name	:	**Beclometasone and Miconazole Ointment_**
1.3 Strength	:	**Beclometasone Dipropionate BP 0.025 % w/w**
		Miconazole Nitrate BP 2.000 % w/w
1.4 Pharmaceutical Form	:	**Ointment**

2. QUALITATIVE & QUANTITATIVE COMPOSITION:

Beclometasone Dipropionate	BP	0.025 %	w/w
Miconazole Nitrate	BP	2.000 %	w/w
Chlorocresol (as preservative)	BP	0.250 %	w/w
Water miscible base			q.s.

3. PHARMACEUTICAL FORM

Ointment

White coloured, smooth perfumed Ointment.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Beclomin Duo Ointment is indicated in infected inflammatory dermatoses such as psoriasis, contact dermatitis, atopic dermatitis, neuro dermatitis, lichen planus, seborrheic dermatitis, eczematous infective dermatitis such as eczematous impetigo, sycosis barbae, various tinea (ring worm) infections of skin, diaper dermatitis and other mucocutaneous candidiasis.

4.2 Posology and method of administration

Puncture the tube nozzle before use. Apply ointment gently to the affected areas with friction in the scalp or skin. The usual frequency of application is twice daily especially in the morning and at night or as directed by the physician.

Use within 6 months after first opening of the tube.

4.3 Contraindications:

Beclomin is contraindicated in the presence of tubercular, leprotic or viral infection of the skin or those patients having the history of the sensitivity reaction to any of the components.

4.4 Special warnings and special precautions for use:

Beclomin Duo Ointment should be taken under medical supervision only. If irritation or sensitization occurs with the use, treatment should be discontinued. In the presence of an infection, consult your Doctor and have his advice or instruction. If excessive dryness or increased skin irritation occurs, discontinue the use of this preparation.

4.5 Interaction with other FPPs and other forms of Interaction

The keratolytic effect of salicylic acid facilitates the absorption of topical corticosteroids; however, excessive and prolonged use of topical preparation containing salicylic acid may cause salicylism.

4.6 Pregnancy and lactation

There are no adequate and well-controlled studies in pregnant women. Therefore, Beclomin should be used during pregnancy & lactation only if the potential benefit justifies the potential risk to the fetus. Topical corticosteroids should be wiped off thoroughly prior to breastfeeding if they are being applied to the breast or nipple area. It should be avoided on the nipple.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Adverse reaction that have been reported with the use of topical corticosteroid include burning, itching, irritation, dryness, folliculitis, hypertrichosis, acne form eruption, hypopigmentation, allergic contact dermatitis.

4.9 Overdose

In an accidental overdose, symptomatic treatment should be provided as per direction of physician.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-inflammatory, Anti-fungal

Beclometasone Dipropionate is a synthetic non-fluorinated corticosteroid with powerful anti-inflammatory action. It has a marked vasoconstrictor effect on application and has been shown to be therapeutically active without causing suppression of pitutory adrenal axis. It has shown excellent results in steroid responsive dertmatoses.

Miconazole Nitrate: A broad spectrum anti-mycotic, having high anti-fungal activity against dermatophytes (yeasts & other phycomycetes like ascomycetes, adelomycetes) and candida species with potent antibacterial activity particularly against gram-ve bacilli and cocci.

5.2 Pharmacokinetic properties

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

Miconazole Nitrate: There is little absorption through skin or mucous membranes when miconazole nitrate is applied topically. 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 faeces as both unchanged drug and metabolites.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

SN	Ingredients	Spec.
01.	Chlorocresol	BP
02.	White Petroleum Jelly (White Soft Paraffin)	BP
03.	Cetomacrogol Emulsifying Wax	BP
04.	Liquid Paraffin (H)	BP
05.	Propylene Glycol	BP
06.	Disodium Edetate (Disodium E.D.T.A.)	BP
07.	Perfume Lavender Prima Compound (5029)	IH
08.	Purified Water	BP

6.2 Incompatibilities

Not Known

6.3 Shelf life

24 months

6.4 Special precautions for storage

Do not Freeze. Protect from light. Keep Out of reach of Children. Store at a temperature not exceeding 30°C.

Use within 6 months after first opening of the tube.

6.5 Nature and contents of container

15 g. in an aluminium lacquered collapsible tube in an inner carton.

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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Country	:	INDIA

8. MARKETING AUTHORISATION NUMBER

09443/10441/NMR/2022

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Jan 25, 2024

10. DATE OF REVISION OF THE TEXT

01/01/2023