SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :

1.1 Brand Name : **Beclomin Lotion**
1.2 Generic Name : Beclomethasone & Miconazole Lotion
1.3 Strength : Beclomethasone Dipropionate 0.025% w/v +
Miconazole Nitrate 2.000% w/v
1.4 Pharmaceutical Form : Lotion

2. QUALITATIVE & QUANTITATIVE COMPOSITION :

Beclomethasone Dipropionate	BP	0.025 % w/v
Miconazole Nitrate	BP	2.000 % w/v
Aqueous base		q.s.
Preservative:		
Chlorocresol	BP	0.200% w/v

3. PHARMACEUTICAL FORM

Lotion
White coloured, perfumed lotion.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Beclomin lotion has potent anti-inflammatory, anti-allergic, anti-fungal and anti-candidal activities. For inflammatory and dermatological conditions threatened with or complicated by microbial and fungal infections. In hairy regions and flexures with fungal dermatoses having an inflammation such as tinea infections, eczema, also indicated for fungal otitis externa etc.

4.2 Posology and method of administration

Beclomin lotion: Apply gently few drops of lotion to the affected areas without friction into the scalp or skin. The usual frequency of application is twice daily especially in the morning and at night.

4.3 Contraindications:

Beclomethasone & Miconazole lotion 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:

This preparation should be taken under medical supervision only. If irritation or sensitization occurs with the use of Beclomin lotion, 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 these preparations. Occlusive dressing should be avoided with Beclomin lotion. Beclomin lotion is not for opthalmic use. Avoid contact with eyes and mucous membranes. If occurs wipe with plenty of clean water.

4.5 Interaction with other FPPs 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 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.

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. 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

None stated.

4.8 Undesirable effects

Undesirable effects that have been reported with the use of topical corticosteroid include burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneform eruption, hypopigmentation, allergic contact dermatitis.

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-inflammatory, Anti-fungal.

Mechanism of action:

Beclomethasone 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.	P.E.G.- 400 (Macrogol-400)	BP
02.	Macrogol Cetostearyl Ether (Cetomacrogol-1000)	BP
03.	Cetostearyl Alcohol	BP
04.	White Petroleum Jelly (White Soft Paraffin)	BP
05.	Polysorbate	BP
06.	Chlorocresol	BP
07.	Sodium Phosphate	BP
08.	Perfume Lavender Prima Comp.(5029)	IH
09.	Purified Water	BP

6.2 Incompatibilities

Not Known

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C. Protect from light. Keep container tightly closed. Keep out of reach of children.

6.5 Nature and contents of container

15ml. LDPE bottle packed in an inner carton.
30 ml. LDPE bottle packed in an inner carton.

6.6 Instructions for use and handling

Shake well before use. For external use only.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

LEBEN LABORATORIES PVT. LTD.,

Business Address:

RO & Works : Plot No. L-4 & L-15, Phase-III, MIDC,
AKOLA–444 104 (MS), INDIA
Ph.:0091-724-2259401/02/03 & Fax: 0091-724-2258371
E-mail- export@lebenlab.com, qad@lebenlab.com, ra@lebenlab.com

Mumbai Off. : 11, Mahavir Mansion, 70, Trinity Street, Near Metro Cinema,
MUMBAI–400 002 (MS), INDIA
Ph.: 0091-22-2207-5301, 02, Fax: 0091-22-2207-5303
E-mail – mumbai@lebenlab.com.

Country : INDIA

8. MARKETING AUTHORISATION NUMBER

06246/07816/REN/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Jul 24, 2021

10. DATE OF REVISION OF THE TEXT
01/01/2023