SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :

1.1 Brand Name : **Canben Cream**
1.2 Generic Name : **Clotrimazole Cream BP 1% w/w**
1.3 Strength : **1.0% w/w**
1.4 Pharmaceutical Form : **Topical Cream**

2. QUALITATIVE & QUANTITATIVE COMPOSITION :

Clotrimazole	BP	1% w/w
Benzyl Alcohol	BP	1% w/w
Cream base		q.s.

3. PHARMACEUTICAL FORM

Topical Cream
White coloured perfumed smooth cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Canben (Clotrimazole Cream) is indicated for the treatment of fungal skin infections of all dermatomycoses due to moulds and other fungi (e.g. Trichophyton species), yeasts (Candida species), skin diseases showing secondary infection with these fungi, candidal nappy rash, balanitis.

4.2 Posology and method of administration

Fungal Infection: The cream should be applied thinly and evenly to the affected area 2 – 3 times daily and rubbed in gently or as prescribed by Physician. If the feet are infected, they should be thoroughly washed and dried, especially between the toes, before applying the cream. Treatment should be continued for at least one month for dermatophyte infections, or for at least two weeks for candidal infections.

4.3 Contraindications

Do not use the Clotrimazole cream to treat nail or scalp infections.

4.4 Special warnings and special precautions for use

Contact with eyes and mucous membranes should be avoided. If a reaction suggesting sensitivity or chemical irritation occurs with the use of Clotrimazole Cream, treatment should be discontinued, the product should be wiped off and appropriate alternative therapy for the infection instituted.

4.5 Interaction with other FPPs and Other forms of Interaction

Laboratory tests have suggested that, when used together, this product may cause damage to latex contraceptives. Consequently the effectiveness of such contraceptives may be reduced. Patients should be advised to use alternative precautions for at least five days after using this product.

4.6 Pregnancy and lactation

Pregnancy: At the low systemic exposures of clotrimazole following topical treatment, harmful effects with respect to reproductive toxicity are not predicted. Clotrimazole can be used during pregnancy, but only under the supervision of a physician or midwife.

Lactation: Clotrimazole Cream should be wiped off thoroughly prior to breastfeeding if they are being applied to the breast or nipple area.

4.7 Effects on ability to drive and use machines

Not Known

4.8 Undesirable effects

Clotrimazole Cream may show side effects like oedema, pain, paraesthesia, skin reactions.

4.9 Overdose & Treatment

No risk of acute intoxication is seen as it is unlikely to occur following a single dermal application of an overdose or inadvertent oral ingestion. There is no specific antidote. However, in the event of accidental oral ingestion, symptomatic treatment should be provided as per direction of physician.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties:

Pharmacotherapeutic group: Antifungal.

ATC Code: A01AB18

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the fungal cytoplasmic membrane.

Clotrimazole has a broad antimycotic spectrum of action *in vitro* and *in vivo*, which includes dermatophytes, yeasts, moulds, etc.

Under appropriate test conditions, the MIC values for these types of fungi are in the region of less than 0.062-8.0 µg/ml substrate. The mode of action of clotrimazole is primarily fungistatic or fungicidal depending on the concentration of clotrimazole at the site of infection. *In vitro* activity is limited to proliferating fungal elements; fungal spores are only slightly sensitive

5.2 Pharmacokinetic properties

Pharmacokinetic investigations after dermal application have shown that clotrimazole is minimally absorbed from the intact or inflamed skin into the human blood circulation. The resulting peak serum concentrations of clotrimazole were below the detection limit of 0.001 mcg/ml, suggesting that clotrimazole applied topically is unlikely to lead to measurable systemic effects or side effects.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

SN	Ingredients	Spec.
01.	Benzyl Alcohol	BP
02.	Cetomacrogol Emulsifying Wax	BP

03.	Light Liquid Paraffin	BP
04.	Propylene Glycol	BP
05.	White Soft Paraffin	BP
06.	Anhydrous Sodium Dihydrogen Phosphate	BP
07.	Phosphoric Acid	BP
08.	Perfume Spring Awakening	BP
09.	Purified Water	BP

6.2 Incompatibilities

Not sufficient data available

6.3 Shelf life

36 month from the date of manufacturing.

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

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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8. MARKETING AUTHORISATION NUMBER

AMD/12/2002 & AMD/6/2002
06879/08845/nmr/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

AMD/12/2002 & AMD/6/2002:

a) Date of first authorization: 21/01/1989.

b) Date of latest renewal: 01/01/2018.

10 DATE OF REVISION OF THE TEXT

01/01/2023