SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

CLOTRISCOT (Clotrimazole Cream USP 1%)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative declaration

Clotrimazole USP	1% w/w
Preservative:	
Chlorocresol USNF	0.1% w/w
In a Cream base with	
Propylene Glycol USP	q.s.

3. PHARMACEUTICAL FORM

Topical Formulation.

Visual/ Physical description of FPP: White coloured Semisolid mass filled in Printed Laminated Tubes.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Clotrimazole Cream USP 1% is used in the treatment of:

i. All dermatomycoses due to moulds and other fungi (e.g. Trichophyton species)

ii. All dermatomycoses due to yeasts (Candida species). These include ringworm (tinea) infections (e.g. athlete's foot), paronychia, pityriasis versicolor, erythrasma and intertrigo.

iii. Skin diseases showing secondary infection with these fungi.

iv. Candidal nappy rash, vulvitis and balanitis.

4.2 Posology and Method of Administration

Posology

There is no separate dosage schedule for the young or elderly.

Method of administration

The cream should be applied thinly and evenly to the affected area 2 – 3 times daily and rubbed in gently. A strip of cream (½ cm long) is enough to treat an area of about the size of the hand.

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 Contra-indications

Hypersensitivity to the active substance or to any of the excipients.
Do not use the cream to treat nail or scalp infections.

4.4 Special Warnings and Special Precautions for Use

This product contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

4.5 Interaction with Other Medicinal Products 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

There is a limited amount of data from the use of clotrimazole in pregnant women. Animal studies with clotrimazole have shown reproductive toxicity at high oral doses. 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:

Available pharmacodynamic/toxicological data in animals have shown excretion of clotrimazole/metabolites in milk after intravenous administration. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from clotrimazole therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Fertility:

No human studies of the effects of clotrimazole on fertility have been performed; however, animal studies have not demonstrated any effects of the drug on fertility.

4.7 Effects on Ability to Drive and Use Machines

Clotrimazole cream has no or negligible influence on the ability to drive or use machines.

4.8 Undesirable Effects

As the listed undesirable effects are based on spontaneous reports, assigning an accurate frequency of occurrence for each is not possible.

Immune system disorders: allergic reaction (syncope, hypotension, dyspnoea, urticaria)

Skin and subcutaneous tissue disorders: blisters, discomfort/pain, oedema, erythema, irritation, peeling/exfoliation, pruritus, rash, stinging/burning.

4.9 Overdose

No risk of acute intoxication is seen as it is unlikely to occur following a single dermal application of an overdose (application over a large area under conditions favourable to absorption) or inadvertent oral ingestion. There is no specific antidote.

However, in the event of accidental oral ingestion, routine measures such as gastric lavage should be performed only if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). Gastric lavage should be carried out only if the airway can be protected adequately.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Pharmacotherapeutic group: Antifungals for topical use – imidazole and triazole derivatives.
ATC Code: D01A C01.
Mechanism of Action
Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the cytoplasmic membrane.

Pharmacodynamic Effects
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.
In addition to its antimycotic action, clotrimazole also acts on gram-positive microorganisms (Streptococci / Staphylococci / Gardnerella vaginalis), and gram-negative microorganisms (Bacteroides).

In vitro clotrimazole inhibits the multiplication of Corynebacteria and gram-positive cocci - with the exception of Enterococci - in concentrations of 0.5-10 µg/ml substrate.

Primarily resistant variants of sensitive fungal species are very rare; the development of secondary resistance by sensitive fungi has so far only been observed in very isolated cases under therapeutic conditions.

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

Non-clinical data reveal no special hazard for humans based on studies of repeated dose toxicity, genotoxicity and carcinogenicity.

Clotrimazole was not teratogenic in reproductive toxicity studies in mice, rats and rabbits. In rats high oral doses were associated with maternal toxicity, embryotoxicity, reduced fetal weights and decreased pup survival.

In rats clotrimazole and/or its metabolites were secreted into milk at levels higher than in plasma by a factor of 10 to 20 at 4 hrs after administration, followed by a decline to a factor of 0.4 by 24 hrs.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sodium Metabisulphite	BP
Chlorocresol	USNF
Disodium Edetate	BP
Cetostearyl Alcohol	USNF
Cetomacrogol Emulsifying wax (C.M. 1000)	BP
Liquid Paraffin	BP
Propylene Glycol	USP
Purified water	USP

6.2 Incompatibilities

None known.

6.3 Shelf Life

36 Months

6.4 Special Precautions for Storage

Store at temperature below 30ºC. Do not freeze.

6.5 Nature and Contents of Container

30gm tube packed in a carton along with leaflet.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Scott-Edil Pharmacia Ltd.
56, EPIP, Phase-I, Jharmajri, Baddi, Distt. Solan (H.P.), 173205, INDIA.

8. MARKETING AUTHORISATION NUMBER

07986/09720/NMR/2022

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Oct 23, 2022

10. DATE OF REVISION OF THE TEXT

Not Applicable