1. NAME OF THE MEDICINAL PRODUCT

CURODERM® CREAM

Strength

Each gram of Curoderm cream contains:

Clotrimazole 1%w/w

Cream base to 100% w/w

Pharmaceutical/Dosage form

Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of Curoderm cream contains:

Clotrimazole 1%w/w

Cream base to 100% w/w

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream

Smooth, uniform, white, almost odourless cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Curoderm cream is indicated in treatment of fungal skin infections (dermatomycoses) due to

- Dermatophytes (e.g. Trichophyton species)
- Yeast (e.g. Candida species)
- Moulds and other Fungi)
- Skin diseases showing secondary infections with these fungi.

Examples of the above listed dermatomycoses include the following:
Interdigital mycoses (e.g. Athlete's foot), Paronychias (associated with nail mycoses), fungal infections in the skin fold, Candida vulvitis, Candida balanitis, Pityriasis versicolor and erythrasma.

4.2 Posology and method of administration

Curoderm cream should be thinly and evenly applied to the affected skin area and rubbed in gently, two to three times daily or as prescribed by the doctor. Duration of treatment could be up to 2-4 weeks depending on the extent and localization of the disease. In fungal infections of the feet, treatment should be continued for about two weeks after the disappearance of all signs of the disease so as to prevent relapse. The feet should be washed and dry thoroughly, especially between the toes, before applying the cream.

4.3 Contra-indications

Curoderm cream is contra-indicated in individuals with history of hypersensitivity to Clotrimazole or any other component of the cream.

4.4 Special warnings and precautions for use

This product contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis). The cream also contains benzyl alcohol which may cause allergic reactions and mild. Local irritation.
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 Fertility, 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 (see section 5.3). 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:

There are no data on the excretion of clotrimazole into human milk. However, systemic absorption is minimal after administration and is unlikely to lead to systemic effects. Clotrimazole may be used during lactation.

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

4.8 Undesirable effects
When applied as recommended, Croderm cream is well tolerated, and no Systemic effects are to be expected with the topical application. If you experience local irritation or allergic reaction after you start using Croderm cream, discontinue treatment and inform your doctor

4.9 Overdose
No risk of acute intoxication is seen as 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

Mechanism of Action

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

Pharmacodynamics Effects

Croderm cream 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 µ g/ml substrate.

The mode of action of Croderm cream is primarily fungistatic or fungicidal depending on the concentration of Croderm cream 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, Croderm cream 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 µ g/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 Croderm cream is minimally absorbed from the intact or inflamed skin into human blood circulation. The resulting peak serum concentrations of Croderm cream were below the detection limit of 0.001 mcg/ml, suggesting that Croderm cream 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.

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

In rats Croderm cream 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:

S. No	Excipients	Standard
1.	Benzyl Alcohol	**BP**
2.	Cetostearyl Alcohol	**BP**
3.	Polysorbate 80	**BP**
4.	Cetomacrogol 1000	**BP**
5.	Liquid Paraffin	**BP**
6.	White soft paraffin	**BP**
7.	Purified Water	**BP**

6.2 Incompatibilities
Not Applicable.

6.3 Shelf life
36 months

6.4 Special precautions for storage
Store below 30^0C.
Keep all medicines out of reach of children.

6.5 Nature and contents of container
The product is presented in 20g Tubes.

6.6 Special precautions for disposal and other handling
No special requirements. Any unused product or waste material should be disposed of in accordance with local requirement.

7. APPLICANT/HOLDER OF CERTIFICATE PRODUCT REGISTRATION.
Unique Pharmaceuticals Limited
11, Fatai Atere Way, Matori-Mushin Lagos
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8. DRUG PRODUCT MANUFACTURER
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9. NAFDAC REGISTRATION NUMBER(S)
A4-1394

10. DATE OF REVISION OF THE TEXT
26/02/2025