SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICALPRODUCT

Mycoril1% w/w cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Mycoril cream contains 1%w/w clotrimazole.

Excipient(s) with known effect
This product contains butylated hydroxytoluene E321.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream.

White, soft, homogeneous cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Mycoril cream is indicated for the treatment of:
1. All dermatomycoses due to moulds and other fungi (e.g.*Trichophyton* species).
2. All dermatomycoses due to yeasts (*Candida* species).
3. Skin diseases showing secondary infection with these fungi.
4. Candidal nappy rash, vulvitis and balanitis.

4.2 Posology and method of administration

Mycoril cream should be applied thinlytwo to three 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.Treatment should be continued for at least one month for dermatophyte infections and at least two weeks for candidal infections.
If the feet are infected they should be washed and dried, especially between the toes, before applying the cream.

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

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Do not use the cream to treat nail or scalp infections.

4.4 Special warnings and precautions for use

Mycoril cream contains butylated hydroxytoluene E321
May cause local skin reactions (e.g. contact dermatitis), orirritation to the eyes and mucous membranes.

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
Availablepharmacodynamic/toxicological data in animals have shown excretion of clotrimazole/metabolites in milk after intravenous administration (see section 5.3). 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

Mycoril 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, dyspnea, urticaria)

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

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product isimportant. It allows continued monitoring of the benefit/risk balance of the medicinal

product.Healthcare professionals are asked to report any suspected adverse reactions via the nationalreporting system.

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, gastric lavage is rarely required and should be considered only if a life-threatening amount of Clotrimazole has been ingested within the preceding hour or 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 dermatological use, Antifungals for topical use, ATC code: D01AC01

Mechanism of action
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 side 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

Absorption
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 0.001mcg/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

Emulsifying wax
Liquid paraffin
White soft paraffin
Benzyl alcohol
Butylated hydroxytoluene E321
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25 ˚C. Replace cap tightly after use.

6.5 Nature and contents of container

Aluminium tube.Pack-size of 20g cream.

6.6 Special precautions for disposal and other handling

No special requirements.

7.MARKETING AUTHORISATION HOLDER

Remedica Ltd
Aharnon Str.,Limassol Industrial Estate

3056Limassol, Cyprus

8. MARKETING AUTHORISATION NUMBER(S)

04734/06764/REN/2018

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of latest renewal: Oct 6, 2020

10. DATE OF REVISION OF THE TEXT

06/07/2023