

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Dermatin.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Quantity/g

1 g contains:

Ketoconazole 20 mg.

For excipients see 6.1

3. PHARMACEUTICAL FORM

Shampoo

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Mycotic skin infections, seborrhoeic dermatitis, dandruff.

4.2 Posology and method of administration

Infected area or the scalp is washed with the shampoo and left in contact for 3-5 minutes before rinsing.

Tinea versicolor: The shampoo is used for a maximum of 5 days.

Seborrhoeic dermatitis and pityriasis capitis: The shampoo is to be used twice a week for 2-4 weeks and then as required

4.3 Contra-indications

Hypersensitivity to the drug.

4.4 Special warnings and precautions for use.

Prevent contact with eyes. If the shampoo should get into the eyes, they should be bathed with water. Seborrhoeic dermatitis and dandruff are often associated with increased hair shedding but this has occurred very rarely with the use of the shampoo.

If symptoms have not improved after 4 weeks contact your doctor or pharmacist.

4.5 Interactions with other medicinal products and other forms of interactions

To prevent a rebound effect after stopping a prolonged treatment with topical corticosteroids is recommended. Continue applying the topical corticosteroid together with Dermatin shampoo and subsequently, gradually withdraw the steroid therapy over a period of 2-3 weeks.

4.6 Pregnancy and lactation

The drug is not absorbed through the skin, not even in case of prolonged use. The use of the drug during pregnancy and lactation is therefore considered safe.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Up to 4% of patients experience side effects when using the shampoo.

Common (>1%): Skin: Local irritation. Tactile hyperesthesia. Hair shedding. Itching.

Rare (<0,1%): Skin: Discolouration of the hair. Dry crisp hair. Oily hair.

Very rarely, discolouration of the hair has been noticed, mainly in patients with grey or damaged hair.

4.9 Overdose

In the event of accidental ingestion, supportive treatment should be carried out. In order to avoid aspiration, neither emesis nor gastric lavage should be instigated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Therapeutic classification: Dermatologicals – Antifungals for topical use - Ketoconazole

ATC group: D 01 A C 08

Dermatin is an antifungal agent of imidazole class. It is active against most candida strains in addition to various other species of fungi, including dermatophytes such as Tricophyton, Epidermophyton and Microsporum and Pityriasis versicolor. The effects against seborrhoeic dermatitis are believed to be caused by effects on Microsporum in topical administration. Ketoconazole is not absorbed, not even in the case of prolonged use.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium laureth sulphate, disodium laureth sulfosuccinate, PEG-120 methyl glucose dioleate, PEG-7-glyceryl cocoate, imidurea, lauryldimonium hydroxypropyl hydrolysed collagen, cocamide DEA, sodium hydroxide, sodium chloride, erythrosine E127, hydrochloric acid conc., purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at room temperature.

6.5 Nature and contents of container

60 ml and 120 ml white HPDE plastic bottles.

6.6 Instructions for use and handling

No special instructions.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

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Date of first authorisation: 20th May 1998

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10 DATE OF REVISION OF THE TEXT

13th July 2004