SCHEDULING STATUS: **S1**

PROPRIETARY NAME: **ADCO-DERMED**

(AND DOSAGE FORM) **(SHAMPOO)**

COMPOSITION:

Each 1 ml of shampoo contains:

Ketoconazole	20 mg
Preservative:	
Methylhydroxybenzoate	0,2 % m/v

PHARMACOLOGICAL CLASSIFICATION:

A 20.2.2 Fungicides

PHARMACOLOGICAL ACTION:

Ketoconazole is a synthetic imidazole dioxolan derivative, has a potent antifungal activity against dermatophytes, such as *Trichophyton* sp., *Epidermophyton* sp., *Microsporum* sp., and yeasts such as *Candida* sp. and *Malassezia furfur (Pityrosporum ovale)*. Percutaneous absorption of **ADCO-DERMED** shampoo is negligible since blood levels cannot be detected, even after chronic use.

INDICATIONS:

Treatment of infections in which the yeast *Pityrosporum* is involved, such as pityriasis versicolor, seborrhoeic dermatitis and pityriasis capitis.

CONTRAINDICATIONS:

ADCO-DERMED shampoo is contraindicated in individuals who have shown hypersensitivity to any of its ingredients.

WARNINGS:

For external use only.

Avoid contact with eyes.

If a severe rash or irritation appears after application, stop using the shampoo.

DOSAGE AND DIRECTIONS FOR USE:

The affected areas of the skin or the hair should be washed with **ADCO-DERMED** shampoo, which should be left for 3 to 5 minutes before rinsing.

Treatment:

Pityriasis versicolor, once daily for maximum 5 days.

Seborrhoeic dermatitis and pityriasis capitis, twice weekly for 2 to 4 weeks.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

After topical administration of ketoconazole, irritation, dermatitis or a burning sensation has occurred.

Less frequently, mainly in patients with chemically damaged hair or grey hair, a discolouration of the hair has occurred.

Seborrhoeic dermatitis and dandruff are associated with increased hair shedding, and this has also been reported, although less frequently with the use of ketoconazole shampoo.

Irritation may occur when **ADCO-DERMED** shampoo is used immediately after prolonged treatment with topical corticosteroids.

To prevent a rebound effect after stopping a prolonged treatment with topical corticosteroids, it is recommended to continue applying a mild topical corticosteroid in the morning and to apply **ADCO-DERMED** shampoo in the evening, and to subsequently and gradually withdraw the steroid therapy over a period of 2 to 3 weeks.

Although ketoconazole is not absorbed through the skin, the use of **ADCO-DERMED** shampoo, is not recommended during pregnancy, as safety in pregnancy and lactation has not been established.

Avoid contact with the eyes. If this happens, rinse the eyes with water.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See "**SIDE-EFFECTS AND SPECIAL PRECAUTIONS**".

Treatment is symptomatic and supportive.

In the event of accidental ingestion, only supportive measures should be carried out, in order to avoid aspiration, neither emesis nor gastric lavage should be performed.

IDENTIFICATION:

Clear, viscous, honey coloured liquid, sweet floral fragrance.

PRESENTATION:

ADCO-DERMED shampoo is supplied in 100 ml HDPE bottles, containing 80 ml shampoo and 150 ml pyropolene gloss containers.

STORAGE INSTRUCTIONS:

Store in a well-closed container, below 25 °C. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

34/20.2.2/0244

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DATE OF PUBLICATION OF THIS PACKAGE INSERT:

10 October 2001