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DEZOR SHAMPOO

NAME AND STRENGTH OF ACTIVE SUBSTANCE: Ketoconazole 2% w/v.

PRODUCT DESCRIPTION: A red viscous liquid with characteristic odour. Other ingredients are Potassium Sorbate, Sodium Laureth Sulphate, Cocamide DEA, Simethicone Emulsion 30%, PEG-40 Hydrogenated Castor Oil, Panthenol, PEG-120 Methyl Glucose Dioleate, Hydrochloric Acid 37%, Pansee Bleue Parfum RSTT5, Ponceau 4R, Sodium Hydroxide and Purified Water.

PHARMACODYNAMICS : Ketoconazole is an imidazole antifungal agent which interferes with ergosterol synthesis and therefore afters the permeability of the cell membrane of sensitive fungi.

PHARMACOKINETICS : Ketoconazole is a broad-spectrum synthetic antifungal agent which inhibits the growth of the following common dermatophytes and yeasts by altering the permeability of the cell membrane: *Dermatophytes-Trichophyton rubrum, T. mentagrophytes, T. tonsurans, Microsporum canis, M. audouini, M. gypseum and Epidermophyton floccosum; Yeasts-Candida albicans and C. tropicalis* and the organism responsible for tinea versicolor, *Malassezia furfur (Pityrosporum orbiculare).* Ketoconazole 2.0% shampoo may be effective in seborrhoeic dermatitis where yeast *Pityrosporum* is involved. A double-blind study in 50 patients with seborrhoeic dermatitis has shown Ketoconazole 2% cream/shampoo to be as effective as hydrocortisone 1% cream in providing symptomic improvement and to be more effective in reducing the number of yeast cells.

INDICATIONS : Treatment and prophylaxis of infections in which the yeast *Malassezia* (previously called *Pityrosporum*) is involved, such as *Pityriasis versicolor* (localized), seborrhoeic dermatitis and *Pityriasis capitis* (dandruff).

CONTRAINDICATIONS : Ketoconazole shampoo is contra-indicated in individuals who have shown hypersensitivity to any of its ingredients.

ADVERSE EFFECTS : Signs of skin irritation, burning sensation, pruritus, dermatitis were observed in 3% of Ketoconazole treated patients and in 2% of placebo controls during clinical trials.

DRUG INTERACTIONS : Concomitant administration of Ketoconazole with rifampicin results in decreased antifungal activity. Concurrent use of Ketoconazole and Phenytoin may alter serum concentrations of both drugs.

PRECAUTIONS/WARNINGS : Discontinue treatment if irritation or hypersensitivity occurs. Avoid introduction of shampoo into the eyes. Overgrowth of non susceptible organisms may occur with prolonged use of any topical antimicrobial agent including Ketoconazole. Do not use on children under 2 years of age except under the advice and supervision of a doctor.
Use in pregnancy and lactation: Animal studies and studies in human volunteers have failed to demonstrate absorption of Ketoconazole shampoo, however due to the teratogenic nature of the active ingredient, Ketoconazole shampoo should only be used in pregnant or lactating woman if in the judgement of the treating physician, the expected benefits outweigh potential risk.

RECOMMENDED DOSAGE :
Direction of use:
Wash hair and scalp or skin thoroughly with Dezor Shampoo for 3-5 minutes, then rinse clean.
Treatment:
- Pityriasis versicolor: once daily for 5 days.
- Seborrhoeic dermatitis and Pityriasis capitis: twice weekly for 2 to 4 weeks.

Maintenance:
- Pityriasis versicolor: once daily for 3 days during a single treatment course before exposure to sunshine.
- Seborrhoeic dermatitis and Pityriasis capitis: once every one or two weeks.

SYMPTOMS AND TREATMENT FOR OVERDOSE AND ANTIDOTE(S) :
No known information available concerning overdosage in human.

PACKING : 60ml and 120ml white plastic bottles.

STORAGE : Store below 30°C. For external use only. Keep out of reach of children.
Recommended shelf-life: 2 years.

PRODUCT HOLDER & MANUFACTURER :
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