Front

Back

DEZOR PLUS SHAMPOO

DESCRIPTION : An opaque red viscous liquid with characteristic odour containing Ketoconazole 2.0% w/w and Zinc Pyrithione 1.0% w/w with Methylparaben 0.10% w/w and Propylparaben 0.05% w/w as preservatives.

PHARMACODYNAMICS : Ketoconazole, one of the active ingredients of Dezor Plus Shampoo is a broad spectrum antifungal agent. It acts by altering the permeability of yeast and fungal cell membranes. Inhibition of ergosterol biosynthesis, the major sterol of these cell membranes, is accompanied by accumulation of 14-α-methylsterol. Cholesterol is the main sterol component of cell membranes in mammalian cells, whereas ergosterol is the primary component of those in fungal cells. Since the 14-α-demethylation step in ergosterol biosynthesis is cytochrome P_{450} dependent, it has been suggested that Ketoconazole may affect biosynthesis by inhibiting cytochrome P_{450} dependent 14-α-demethylase activity.

This leads to accumulation of 14-α-methylsterols. Accumulation of 14-α-methylsterols, together with the decrease in ergosterol content of the cell membrane, create an unstable condition which leads to disturbed membrane function, compromised cell growth and viability.

At higher concentrations, Ketoconazole caused an accumulation of saturated fatty acids after incubation with *Candida albicans*, an effect that is expected to further destabilize the structure and permeability of the fungal cell membrane.

Thus, Ketoconazole has a dual action; a fungistatic mechanism at low concentrations which seems to be characteristic of all imidazoles and is related to inhibition of ergosterol biosynthesis and a fungicidal effect at higher concentrations, which is directly produced by damage to the cell membrane.

An MIC of 0.02 mcg/ml is sufficient to inhibit the growth of Pityrosporum yeast. Ketoconazole also has the action on 5-lipooxygenase, thus inhibits leukotriene B4 synthesis and thus inflammation.

Zinc Pyrithione, the other active component of Dezor Plus Shampoo reduces flaking and itching caused by dandruff (keratolytic).

Zinc Pyrithione inhibits membrane transport via a direct or indirect effect on the primary proton pump which energies transport and that the site of actions of pyrithione is likely to be intracellular rather then extracellular. Zinc Pyrithione causes the leakage of intracellular material.

Zinc Pyrithione is effective at an MIC of 0.12-8 mcg/ml.

PHARMACOKINETICS : Percutaneous absorption of Ketoconazole and Zinc Pyrithione Shampoo is negligible since blood levels cannot be detected even after chronic shampooing, systemic effects therefore are not expected.

INDICATIONS : Dezor Plus Shampoo is indicated for use in the treatment of Dandruff and Seborrhoeic Dermatitis of scalp.

ROUTE OF ADMINISTRATION : For topical application only.

DOSAGE & ADMINISTRATION : Wet hair and scalp and apply sufficient shampoo to produce enough lather. Massage for one minute and rinse with warm water. Repeat procedure for additional 3 minutes. Rinse with warm water and dry hair. Shampoo twice a week for 4 weeks at least 3 days between uses and then as needed or use as directed by the Physician.

CONTRAINDICATIONS : Dezor Plus Shampoo is contraindicated in persons showing hypersensitivity to Ketoconazole, Zinc pyrithione or the excipients.

ADVERSE EFFECTS : Topical treatment with Dezor Plus Shampoo is well tolerated. In rare instances, discoloration of hair has been observed. Increase in normal hair loss, irritation (<1%), abnormal hair texture, mild dryness of skin, itching, oilyness/dryness of hair and scalp have also been noted. Peripheral neuritis can be seen with Zinc pyrithione, although rarely.

PRECAUTIONS/WARNINGS : For External Use Only. Avoid contact with eyes. If contact occurs, rinse thoroughly with water. If condition worsens or does not improve after regular use of this product as directed, consult a Doctor. There have been reports that use of the shampoo resulted in removal of curl from permanently waved hair. Overgrowth of non-susceptible organisms may occur with prolonged use of any topical antimicrobial agent.

Carcinogenesis, mutagenesis, impairment of fertility : No evidence of carcinogenicity, mutagenicity and impairment of fertility have been reported with topical use of this preparation.

Pregnancy & Lactation : Since Ketoconazole and Zinc pyrithione are not absorbed through the skin after topical application, pregnancy and lactation are not a contraindication for the use of Dezor Plus Shampoo. However, use of the same in the first trimester of pregnancy and in nursing mothers should only be done in close consultation with a Physician.

Paediatric Use : Safety in children has not been established.

DRUG INTERACTIONS : No significant drug interactions have been reported.

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

STORAGE CONDITIONS : Store below 30°C. Protect from light. Keep out of reach of children.

RECOMMENDED SHELF-LIFE : 2 years.

PACKING : 60ml and 120ml white plastic bottles.

MANUFACTURED BY :
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