

DATA SHEET

SEBIZOLE

2% w/w ketoconazole shampoo

Presentation

A clear, pink coloured, viscous liquid with a fragrant smell.

Uses

Actions

Microbiology: 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*, *C tropicalis*, *Pityrosporum ovale* (*Malassezia ovale*) and *P orbiculare* (*M furfur*). Development of resistance to ketoconazole has not been reported. *In vitro* studies suggest that ketoconazole impairs the synthesis of ergosterol, which is a vital component of fungal cell membranes. The mechanism of the therapeutic effect in seborrhoeic dermatitis and dandruff has not been established. It is postulated that the therapeutic effect of ketoconazole in dandruff may be due to the reduction in number of *P ovale*, but this has not been proven.

Pharmacokinetics

Absorption of ketoconazole from shampoo formulations is generally minimal.

Toxicology. Clinical studies showed that the irritancy potential of ketoconazole 2% shampoo was significantly less than that of selenium sulfide 2.5% shampoo.

Human volunteer studies on the potential to cause sensitisation, phototoxicity and photoallergy showed no contact sensitisation of the delayed hypersensitivity type, no phototoxicity and no photoallergenic potential due to ketoconazole 2% shampoo.

Indications

Topical treatment of severe seborrhoeic dermatitis and severe dandruff of the scalp in adults.

For both conditions, Sebizole Shampoo provides only temporary relief during the period of its use. Both conditions relapse soon after discontinuation of treatment. The relapse rate for seborrhoeic dermatitis is not known, but for dandruff it is high within a short time after cessation of treatment.

Dosage and Administration

Sebizole Shampoo should be applied to the wet scalp, worked into a lather and left on for three to five minutes before rinsing thoroughly with water. The use of unnecessarily large quantities of Sebizole Shampoo during treatment should be avoided.

The duration of treatment should be limited to twice weekly for no longer than four weeks at any one time. An interval of at least four weeks should be allowed between consecutive courses.

Contraindications

Hypersensitivity to any ingredient.

Warnings and Precautions

Irritation may occur when Sebizole Shampoo is used immediately after prolonged treatment with topical corticosteroids on the same area. Therefore, it is recommended to wait about two weeks after stopping treatment with topical corticosteroids before using Sebizole Shampoo.

If a reaction suggesting sensitivity or chemical irritation should occur, use of Sebizole Shampoo should be discontinued.

Seborrhoeic dermatitis and dandruff are often associated with increased hair shredding, and this has also been reported, although rarely, with the use of ketoconazole 2% shampoo.

Safety of use beyond four weeks has not been adequately established.

Avoid contact with the eyes. If the shampoo should get into the eyes, they should be bathed with cold water.

Use in Pregnancy

Ketoconazole shampoo does not produce detectable blood levels after topical application. However, due to the teratogenic nature of the active ingredient in rats when given orally, it should only be used in pregnant or lactating women if in the judgment of the treating doctor the expected benefits outweigh the potential risk.

Use in Lactation

See Use in pregnancy.

Adverse Effects

Ketoconazole shampoo is generally well tolerated. Reported adverse events included allergic reaction, itchy, irritated or greasy skin and scalp, rash and erythema. As with other shampoos, a local burning sensation, oiliness and dryness of the hair and scalp have also been reported. In rare instances, mainly in

patients with chemically damaged hair or grey hair, a discolouration of the hair has been observed. One case of exfoliative dermatitis has been reported but its relationship to the use of the shampoo is uncertain.

Overdosage

Symptoms

Oral ingestion is usually followed by nausea and vomiting due to the detergent.

Treatment

In the event of accidental ingestion, only supportive measures should be employed. To avoid aspiration, neither emesis nor gastric lavage should be performed.

Pharmaceutical Precaution

Store below 25°C.

Medicine Classification

Pharmacy Only Medicine

Package Quantities

100 ml bottles.

Further Information

Ketoconazole's chemical name: *cis*-1-acetyl-4[4-[[2-(2,4-di-chlorophenyl)-2-(1H-imidazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]piperazine. Its molecular formula and weight are C₂₆H₂₈Cl₂N₄O₄ and 531.44 respectively.

Other ingredients of the shampoo are: Sodium laureth sulfate, Cocamide DEA, sodium lauroyl sarcosinate, PEG-150 distearate, hydrochloric acid, Germall II (preservative), Flairoma perfume compound herb fragrance 5086, erythrosine sodium, micropure potable water.

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