

# **ORAZOLE**

**Shampoo**

## **Composition**

Ketoconazole 2%

## **Action**

Ketoconazole is a broad-spectrum synthetic antifungal agent that 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.

Ketoconazole impairs the synthesis of ergosterol, which is a vital component of fungal cell membranes. The mechanism of the therapeutic effect in seborrheic 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. Absorption of ketoconazole from shampoo formulations is generally minimal.

## **Indications**

Orazole is a medicine used for the prevention and treatment of dandruff caused by fungal infections of the scalp, as well as for the relief of associated symptoms such as flaking, scaling, and itching.

## **Contraindications**

Known hypersensitivity to ketoconazole or any of the other ingredients that may be recognized by severe itching and redskin after application of the shampoo.

## **Warnings**

As with other shampoos, avoid contact in the eyes. If this happens, however, rinse the eyes with water. If a severe rash or irritation appears after application, stop using the shampoo.

## **Adverse Reactions**

A local burning sensation, itching, contact dermatitis (due to irritation or allergy), or oily hair may occur on exposed areas.

## **Precautions**

Although ketoconazole is not absorbed through the skin, the use of Ketoconazole is not recommended during pregnancy, as safety in pregnancy and lactation has not been established.

## **Dosage and Administration**

Wet the hair. Apply sufficient shampoo to produce a generous lather. Gently massage over the entire scalp. Allow the shampoo to soak in for 3 to 5 minutes before rinsing.

Use regularly, at least twice a week for 8 weeks to treat the infection. To prevent the infection reappearing, use once a week or once every two weeks.

## **Presentation**

Plastic bottle of 100 ml