

Lotion Ketrazole (Ketoconazole)

Shampoo Based Scalp Lotion

کیترازول لوشن
(کیتوکونازول)

COMPOSITION

Each gram contains:

Ketoconazole.....20mg

(BP Specifications)

DESCRIPTION

Ketrazole lotion contains Ketoconazole as an active component. It is a broad spectrum antifungal in a shampoo based aqueous suspension. It is for topical application to treat seborrheic dermatitis and fungal skin infections.

INDICATIONS

Ketoconazole Shampoo based lotion is indicated for the treatment and prevention of seborrheic dermatitis, pityriasis capitis (dandruff) and pityriasis versicolor that may be associated with the fungus *Pityrosporum*.

MECHANISM OF ACTION

Ketoconazole is an imidazole-dioxolane antimycotic, active against yeasts, including *Malassezia* and dermatophytes. Its broad spectrum of activity is already well known. Ketoconazole also has a direct anti-inflammatory action independent from its antifungal activity which may contribute to symptom relief in dandruff and seborrheic dermatitis.

DOSAGE & ADMINISTRATION

For topical administration.

Adults including the elderly and adolescents: Wet hair and scalp thoroughly with water. Apply sufficient shampoo based lotion to produce enough lather to wash the scalp and hair, gently massage it over the entire scalp and leave for 3-5 minutes before rinsing thoroughly.

Seborrheic dermatitis and dandruff: Use Ketoconazole shampoo based lotion twice weekly for 2-4 weeks.

Prophylaxis: Use Ketoconazole shampoo based lotion once every 1-2 weeks.

Pityriasis versicolor: Use Ketoconazole shampoo based lotion once daily for a maximum of 5 days.

Prophylaxis: As patches of pityriasis versicolor become more apparent on exposure to the sun. Ketoconazole 2% w/w shampoo based lotion may be used once daily for a maximum of 3 days in a single treatment course before exposure to sunshine.

Pediatric population: The safe and effective use of Ketoconazole 2% w/w shampoo based lotion in infants and children under the age of 12 years has not been established.

PHARMACOKINETICS

Ketoconazole does not appear to be appreciably absorbed systemically following topical application of a 2% shampoo to skin. Ketoconazole was not detected in plasma of patients receiving topical application of 2% shampoo 4-10 times weekly for 6 months, or in patients using 2% shampoo 2-3 times weekly for an average of 16 months. Following a single topical application, substantial amounts of the drug were detected in hair 12 hours after application; however only 5% of the applied ketoconazole was detected in hair keratin. Following repeated (twice weekly for 2 months) application, 20% of the applied dose was detected in hair keratin.

WARNINGS & PRECAUTIONS

In patients who have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over a period of 2 – 3 weeks, while using Ketoconazole shampoo based lotion, to prevent any potential rebound effect.

Ketoconazole shampoo based lotion may be irritating to mucous membranes of the eyes and contact with this area should be avoided. If Ketoconazole shampoo based lotion does get into the eyes, they should be bathed gently with cold water. This medicine contains 5.00 mg benzyl alcohol in each

gram which is equivalent to 0.50% w/w. Benzyl alcohol may cause allergic reactions and mild local irritation.

Pregnancy and lactation: Ketoconazole shampoo based lotion is not detected in plasma after chronic shampooing or topical application. Ketoconazole shampoo based lotion is not contraindicated for pregnancy or lactation but caution should be exercised.

SIDE EFFECTS

Immune System Disorders:

Hypersensitivity

Nervous System Disorders:

Dysgeusia

Infections and Infestations:

Folliculitis

Eye Disorders:

Increased lacrimation, Eye irritation

Skin and Subcutaneous Tissue Disorders:

Alopecia, Dry Skin, abnormal hair texture, Rash, Skin burning Sensation, Acne, contact dermatitis, Skin disorder, Skin exfoliation, Angioedema, Urticaria, Hair color changes.

General Disorders and Administration Site Conditions

Application site erythema, Application site irritation, Application site pruritus, Application site Reaction, Application site hypersensitivity, Application site pustules.

DRUG INTERACTIONS

No interaction studies have been performed.

CONTRAINDICATIONS

Ketrazole lotion is contraindicated in patients with hypersensitivity to ketoconazole or any of the excipients.

STORAGE & INSTRUCTIONS

Do not store above 30°C.

Protect from heat, sunlight and moisture.

Avoid contact with the eyes.

Keep bottle tightly closed.

Keep away from the reach of children.

To be sold on the prescription of a registered medical practitioner only.

HOW SUPPLIED

60ml

خوراک و ہدایات:

دوا کو ۳۰ ڈگری سینٹی گریڈ سے زیادہ درجہ حرارت

پر نہ رکھیں۔ دھوپ، گرمی اور نمی سے بچائیں۔ بوتل

کو مضبوطی سے بند رکھیں۔ بچوں کی پہنچ سے دور

رکھیں۔ صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔

Manufactured by:

PHARMASOL
PRIVATE LIMITED

Plot # 549, Sundar Industrial Estate,
Lahore, Pakistan.