

Drof shampoo

Ketoconazole 2%

Composition:

DROF SHAMPOO

Contains the synthetic broad-spectrum anti-fungal agent ketoconazole 2% .

Each 1 gm contains:
Ketoconazole 20 mg

Action:

Ketoconazole, a synthetic imidazole dioxolane derivative has a potent antifungal activity against dermatophytes such as *Trichophyton* sp., *Epidermophyton* sp., *Microsporum* sp., and yeasts, such as *Candida* sp. and *Malassezia* sp. (*Pityrosporum* sp.). DROF SHAMPOO rapidly relieves scaling and pruritus which are usually associated with seborrhoeic Dermatitis, pityriasis capitis (dandruff) and pityriasis versicolor.

Pharmacokinetics:

Percutaneous absorption of ketoconazole shampoo is negligible as blood levels are not detected even after chronic use.

Systemic effects therefore are not expected.

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).

Dosage and Administration:

The affected areas of the skin or the scalp should be washed with DROF SHAMPOO which should be left on the skin, scalp for 3 – 5 minutes before rinsing.

Treatment:

- Pityriasis versicolor: once daily for 5 days.
- Seborrhoeic dermatitis and pityriasis capitis: twice weekly for 2 – 4 weeks.

Prophylaxis:

- Pityriasis versicolor: once daily for 3 days during a single treatment course before the summer.
- Seborrhoeic dermatitis and pityriasis capitis: once every 1 or 2 weeks.

Contraindications:

Known hypersensitivity to ketoconazole.

Warning and 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have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over a period of 2 – 3 weeks, while using DROF SHAMPOO to prevent any potential rebound effect.

Increase hair shedding is often associated with seborrhoeic dermatitis and dandruff and has been rarely reported with the use of DROF SHAMPOO.

Avoid contact with the eyes, in case of contact with eyes, rinse with plenty of water.

Pregnancy and Lactation:

Since ketoconazole is not absorbed through the skin after topical application, Pregnancy and lactation are not a contraindication for the use of DROF SHAMPOO.

Adverse reactions:

Topical treatment with DROF SHAMPOO is generally well tolerated.

As with other shampoo, a local burning sensation, itching or contact dermatitis (due to irritation or allergy) may occur on exposed areas. Oily and dry hair have been reported rarely with the use of DROF SHAMPOO.

In rare instances, mainly in patients with chemically damaged hair or gray hair, a discoloration of the hair has been observed with the use of DROF SHAMPOO.

Overdosage:

Not expected as DROF SHAMPOO is intended for external use only.

In the event of accidental ingestion, only supportive measures should be carried out.

In order to avoid aspiration, neither emesis nor gastric lavage should be performed.

Package:

Plastic containers with 100 ml DROF SHAMPOO.

Storage:

Store between 15 - 25°C.
Keep out of reach of children.

Instruction for use:

The infected part of the skin should be washed with DROF SHAMPOO allowing the product to soak in for 3 – 5 minutes before rinsing, the skin itself should be thoroughly washed not just the hair.

FOR EXTERNAL USE

This is a medicament

- Medicament is a product which affects your health, and its consumption contrary to instruction is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the Pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep the medicament out of reach of children

Council of Arab Health Ministers & Union of Arab Pharmacists



Manufactured by: DEEF pharmaceutical industries Co. Saudi Arabia - Al Qassim - Al Badaye