

**INSTRUCTION
for medical use**

DERMAZOLE® PLUS

Composition:

substances: ketoconazole, zinc pyrithione;

1 ml of shampoo contains 20 mg of ketoconazole, 48 % water suspension of zinc pyrithione equivalent to 10 mg of zinc pyrithione;

excipients: cocodietanolamide, sodium laureth sulfate, disodium monolauril sulfosuccinate, macrogol 120 methylglucose dioleate, propylene glycol, hydrochloric acid, sodium chloride, sodium hydroxide, butylated hydroxytoluene (E 321), imidurea, Ponceau 4R (E 124), Aloe Vera powder, flavor AL012514, purified water.

Pharmaceutical form. Shampoo.

Basic physical and chemical properties: pink viscous liquid with a characteristic odor.

Pharmacotherapeutic group. Antifungals for topical use.

Code ATC ATX D01A C.

Pharmacological properties.

Pharmacodynamics.

Pharmacological properties of the shampoo are due to the properties of the active substances included in its formulation: ketoconazole and zinc pyrithione.

Ketoconazole is a synthetic derivative of imidazole-dioxolane, providing fungicidal and fungistatic activity against dermatophytes (*Epidermophyton spp.*, *Microsporum spp.*, *Trichophyton spp.*), yeast and yeast-like fungi of different strains (*Candida spp.*, *Malassezia furfur* – *Pitysporum ovale*).

When applied topically, zinc pyrithione has antimicrobial and antifungal action; effective against streptococci, staphylococci, fungi and other pathogens. Zinc pyrithione determines anti-seborrheic effect of the drug and has therapeutic effect against seborrheic dermatitis and dandruff. Shampoo with ketoconazole reduces flaking and itching, which is often associated with dandruff, seborrheic dermatitis and tinea versicolor.

Aloe Vera powder promotes hair moisturizing, its enrichment with vitamins and microelements.

Pharmacokinetics.

No special studies of pharmacokinetics of the shampoo have been conducted, but it is known that when applied topically, ketoconazole and zinc pyrithione are practically not absorbed into the systemic circulation and have no systemic effect.

Clinical characteristics.

Indications.

Treatment and prevention of fungal diseases of the scalp which are accompanied by flaking and itching, such as:

- dandruff;
- seborrheic dermatitis;
- localized tinea versicolor of the scalp.

Contraindications.

Hypersensitivity to ketoconazole, zinc pyrithione or any other component of the drug.

Interaction with other medicinal products and other forms of interaction.

When prescribing Dermazole Plus in patients that have been treated with topical glucocorticosteroids for a long time, treatment with the latter should be continued and they should be gradually withdrawn during 2-3 weeks (to avoid the withdrawal syndrome).

Taking into account lack of significant systemic absorption, interaction with other medicinal products is unlikely.

It is not recommended to use it concomitantly with dermatological preparations containing glucocorticosteroids.

Peculiarities of use.

The drug is intended only for external use.

When using the drug, avoid its contact with eyes and mucous membranes.

In case of contact with eyes, wash them thoroughly with water.

Seborrheic dermatitis and dandruff are often accompanied by increased hair loss, which can in some cases continue for some time at the beginning of application of the shampoo.

The drug contains butylated hydroxytoluene (E 321), which may cause local skin reactions (e.g. contact dermatitis) or irritation of the eyes and mucous membranes.

Using during pregnancy or breastfeeding.

During pregnancy or breastfeeding the drug may be used only in case when the expected benefit for the mother overweight the potential risk for the fetus/child.

Effect on reaction rate when driving motor transport or operating other mechanisms.

Has no effect.

Administration and dosage.

Before using, shake well the shampoo.

Apply the shampoo on wet hair and scalp for 3-5 minutes, and then rinse with water.

Recommended application regimen for adults:

<i>Indications</i>	<i>Treatment</i>	<i>Prevention</i>
Dandruff.	2 times per week during 2-4 weeks;	1 time per week or 1 time per 2 weeks
Seborrheic dermatitis.		
Tinea versicolor.	every day during 5 days.	every day during 3 days (single treatment course) before the summer season

Children.

There is no experience of using the drug in children.

Overdose.

As the shampoo is for external use only, and ketoconazole is practically not absorbed into the systemic circulation, development of overdose symptoms is unlikely. In case of accidental ingestion of the shampoo, only supportive and symptomatic measures are used. Do not induce vomiting and perform gastric lavage to prevent aspiration.

Adverse reactions.

Skin and subcutaneous tissue: erythema, burning sensation of the skin, itching, acne, contact dermatitis, skin irritation, rash, pustular rash at the application site, urticaria, xerosis, skin flaking enhancement, sense of discomfort, hypersensitivity, changes in the skin.

Appendages of skin: change in the hair structure, excessive hair dryness or oiliness, hair loss (alopecia), change in the hair color (generally in patients with chemically damaged or gray hair), nail discoloration. Cases of straightening of naturally curly hair are known.

Nervous system: taste perversion (dysgeusia), paresthesia, hypersensitivity.

Immune system: hypersensitivity reactions, including anaphylactoid reactions, angioedema.

Organs of vision: eye irritation, eyelid edema, excessive tearing.

Infections and invasions: folliculitis.

Shelf-life. 3 years.

Storage conditions.

Store at the temperature not more than 25 °C in the original package.

Keep out of reach of children.

Package.

50 ml or 100 ml are in bottles neck bottles covered with shrink wrapped cap.

1 bottle in a carton package.

Condition of supply.

Without prescription.

Manufacturer.

KUSUM HEALTHCARE PVT LTD.

Address.

SP-289 (A), RIICO Industrial area, Chopanki, Bhiwadi, Dist. Alwar (Rajasthan), India.

Date of last revision.