

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Dermazole Plus 20 mg/10 mg Shampoo

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of shampoo contains:

Ketoconazole USP 20 mg

Zinc pyrithione suspension 48% equivalent to Zinc pyrithione 10 mg.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Shampoo.

Pink coloured viscous liquid with specific odor.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

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

4.2 Posology and method of administration

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

Paediatric:

There is no experience of using the drug in children.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

The product is intended only for external use.

When using the shampoo, avoid contact of the drug 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 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.

4.5 Interaction with other medicinal products and other forms of interaction

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topical Glucorticosteroids for a long time, treatment with the latter should be continued and they should be gradually withdrawn during 2-3 weeks (to avoid the withdrawal syndrome).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

4.6 Pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

Has no effect.

4.8 Undesirable effects

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.

Appendages of skin: folliculitis, hair restructuring, excessive hair dryness or oiliness, hair loss (baldness), change in hair color (generally in patients with chemically damaged or gray hair), nail discoloration. There are known cases of straightening of naturally curly hair.

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

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

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

Infections and invasions: folliculitis.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via EFDA yellow Card Scheme, online at <https://primaryreporting.who-umc.org/ET> or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties. Antifungals for topical use.

ATC Code: D01A C.

5.1 Pharmacodynamic Effects

The 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 externally zinc pyrithione suspension has antimicrobial and antifungal activity; effective towards streptococci, staphylococci, fungi and several other pathogens. Zinc pyrithione determines anti-seborrheic effect of the drug and acts against 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 by vitamins and microelements.

5.2 Pharmacokinetic properties

No special studies of pharmacokinetics of 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.

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cocodiethanolamide, sodium lauryl ether sulphate, disodium monolauryl ether sulfosuccinates, macrogol 120 methylglucose dioleate, propylene glycol, Conc. hydrochloric acid, sodium chloride, sodium hydroxide, butylated hydroxytoluene (E 321), imidurea, Ponceau 4R (E 124), Aloe Vera powder, fragrance AL012514, purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at the temperature below 30°C.

Keep all medicines out of reach of children.

6.5 Nature and contents of container

Shampoo of 50 ml or 100 ml are in bottles. 1 bottle is packed in a carton along with package insert.

6.6 Special precautions for disposal and other handling

Not applicable

7. MARKETING AUTHORISATION HOLDER

Kusum Healthcare Pvt. Ltd.
SP-289(A), RIICO Industrial Area, Chopanki, Bhiwadi, Dist. Alwar (Rajasthan) India

8. MARKETING AUTHORISATION NUMBER(S)

04989/07179/NMR/2019

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 February 2020

10. DATE OF REVISION OF THE TEXT

08/2023

11. REFERENCES

SmPC published on electronic medicines compendium
<https://www.medicines.org.uk/emc#gref>

The MHRA published product information
<https://products.mhra.gov.uk/>

Human medicine European public assessment report
<https://www.ema.europa.eu/en/medicines>