

# Ketoconazole & Zinc pyrithione

## DANDROP SHAMPOO

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**1. NAME OF THE MEDICINAL PRODUCT**

Ketoconazole & Zinc pyrithione

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Ketoconazole.....2.00% w/v

Zinc Pyrithione (ZPTO).....1.00% w/v

In Aloe vera base ..... q.s.

**3. PHARMACEUTICAL FORM**

Shampoo

**4. CLINICAL PARTICULARS**

**4.1 Therapeutic Indications**

Topical treatment of Seborrhoeic Dermatitis including dandruff resulting from proven fungal infection including Pityriasis versicolor.

**4.2 Method of Administration**

SHAKE WELL BEFORE USE

Moisten the hair and scalp thoroughly with water. Apply sufficient lotion to produce enough lather to wash scalp and hair and gently massage it over the entire scalp area for about 1 minute. Rinse hair thoroughly with water.

Repeat the procedure leaving the lotion on scalp for 3 minutes. After the second thorough rinse, dry hair with towel or warm air flow. Use twice a week for 4 weeks with at least 3 days between each application and then intermittently as needed to maintain control or use as directed by physician.

The infected parts of the skin should be washed with DANDROP Shampoo 2%, allowing the product to soak in for 3 to 5 minutes before rinsing. The skin itself should be thoroughly washed, not just the hair.

#### **4.3 Contraindications**

DANDROP Shampoo 2% is contraindicated in individuals with unknown hypersensitivity to any of its ingredients.

#### **4.4 Special Warnings and Special Precautions for Use**

FOR EXTERNAL USE ONLY

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have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over the period of 2 to 3 weeks, while using DANDROP Shampoo 2%, to prevent any potential rebound effect.

Avoid contact with the eyes. If the shampoo gets into the eyes, wash the eyes with copious amount of water.

Interactions with other Medicaments and other forms of Interaction: None known.

#### **4.5 Fertility, Pregnancy and Lactation**

There are no adequate and well-controlled studies in pregnant or lactating women. Plasma concentrations of ketoconazole were not detectable after topical administration of Ketoconazole Shampoo 2% to the scalp of non- pregnant humans.

There are no known risks associated with the use of DANDROP Shampoo 2% in pregnancy or lactation.

#### **Adults, Elderly and Children:**

Use the shampoo twice weekly for 2-4 weeks. Wash affected areas of skin (not just the hair), using a palm full of shampoo and leave for 3-5 minutes before rinsing.

#### **4.8 Undesirable Effects**

Application site erythema, irritation, hypersensitivity, pruritus & pustules may occur

**Others:** Acne, Alopecia, Contact Dermatitis, Dry skin & hair texture, Abnormal skin rash and Skin burning sensation, Skin exfoliation, Unknown Angioedema, Urticaria, Hair color changes

#### **4.9 Overdose**

In the event of accidental ingestion, supportive and symptomatic measures should be carried out. To avoid aspiration, emesis or gastric lavage should be performed.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic Properties**

Ketoconazole, a synthetic imidazole dioxolane derivative, has a potent antifungal activity against dermatophytes, such as *Trichophyton* spp., *Epidermophyton* spp., *Microsporum* spp., and yeasts, such as *Candida* spp. and *Malassezia* spp. (*Pityrosporum* spp.).

Zinc pyrithione is best known for its use in treating dandruff and seborrhoeic dermatitis. It has fungistatic (that is, it inhibits the division of fungal cells) and bacteriostatic (inhibits bacterial cell division) properties and is used in the treatment of seborrhoeic dermatitis. It is effective against many pathogens from the *Streptococcus* and *Staphylococcus* genera.

DANDROP Shampoo 2% rapidly relieves scaling and pruritus, which are usually associated with seborrhoeic dermatitis, pityriasis capitis (dandruff) and pityriasis versicolor.

## **6. PHARMACEUTICAL PARTICULARS**

**6.1 Shelf-life:** 24 months

**6.2 Special Precautions for Storage:** Store below 25°C. Store in a cool and dry place protect from heat and Light

**6.3 Nature and contents of container:** HDPE bottle

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Alkem Labs Limited  
Alkem House;  
SenapatiBapat Marg,  
Lower Parel; Mumbai,  
Maharashtra: 400 013.