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FUNGICIDE & SPOO-KT

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**1. Generic Name**

Ketoconazole With Zinc Pyrithione Lotion

**2. Qualitative and quantitative Composition:**

Ketoconazole I.P. ....2.00 % w/v

Zinc Pyrithione..... 1.00 % w/v

Colour: Brilliant Blue

Conditioner shampoo base..... q.s.

The excipients used are Polyquaternium 7, Sodium Laureth Sulfate, Cocamide MEA, Cocamidopropyl Betaine, Glycol Distearate, and Sodium Chloride, Triethanol Lauryl Sulphate, Carbomer, Citric Acid, Brilliant Blue

**3. Dosage form and strength**

**Dosage form:** Lotion

**Strength:** Ketoconazole 2.00 % + Zinc Pyrithione 1.00 %

**4. Clinical particulars**

**4.1. Therapeutic indication**

For the treatment of pityriasis and dandruff of the scalp.

**4.2. Posology and method of administration**

As directed by the physician.

**4.3. Contraindications**

Hypersensitivity to Ketoconazole, Zinc Pyrithione and other excipients.

**4.4. Special warnings and precautions for use**

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have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over a period of 2 to 3 weeks, while using Ketoconazole with Zinc Pyrithione Lotion, to prevent any potential rebound effect.

Keep out of the reach of eyes. If the lotion gets into the eyes, immediately, the eyes should be rinsed off with water.

**4.5. Drugs interactions**

When prescribed 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topical Glucorticosteroids for a long time, treatment with the latter should be continued and they should be gradually withdrawn for 2-3 weeks (to avoid the withdrawal syndrome).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. Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)**

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**

Spoo-KT has no influence on the ability to drive and use machines.

#### **4.8. Undesirable 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, hair texture abnormal, rash, skin burning sensation, acne, dermatitis contact, skin disorder, skin exfoliation, angioedema, urticaria, hair colour changes.

##### General Disorders and Administration Site Condition

Application site erythema, application site pruritus, application site bleeding, application site discomfort, application site dryness, application site inflammation, application site irritation application site paraesthesia, application site reaction.

#### **Reporting of 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. Report suspected adverse reactions via any point of contact available at [www.torrentpharma.com](http://www.torrentpharma.com).

#### **4.9. Overdose**

Excessive topical application may lead to erythema, oedema, and a burning sensation, which will disappear upon discontinuation of the treatment.

##### Ingestion

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

### **5. Pharmacological properties**

#### **5.1. Mechanism of Action**

Ketoconazole is a synthetic derivative of imidazole-dioxolane, providing fungicidal and fungistatic activity. Zinc pyrithione suspension has antimicrobial and antifungal activity.

## 5.2. Pharmacodynamic properties

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* – *Pityosporum 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.

## 5.3. 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.

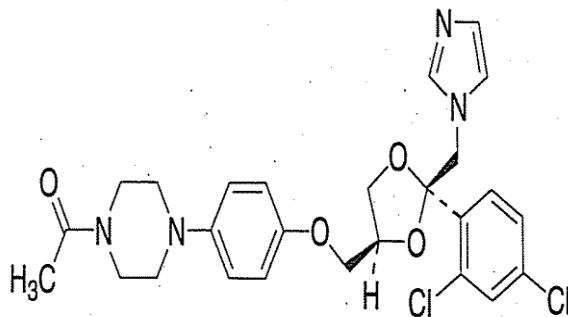
## 6. Nonclinical properties

### 6.1. Animal Toxicology or Pharmacology

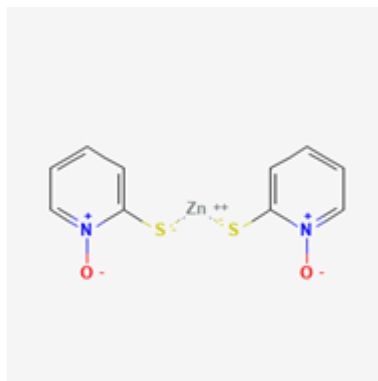
Not applicable

### 7. Description

Ketoconazole is cis-1-acetyl-4-[[[(2RS,4RS)-2-(2,4-dichloro-phenyl)-2-(1H-imidazol-1-ylmethyl)-1,3-dioxolan-4-yl] phenyl]piperazine. Having molecular weight 531.4 and its empirical formula is  $C_{26}H_{28}Cl_2N_4O_4$ . The structural formula is:



Zinc Pyrithione is zinc bis(1-oxidopyridin-1-ium-2-thiolate). Having molecular weight 317.7 g/mol and its empirical formula is  $C_{10}H_8N_2O_2S_2Zn$ . The structural formula is:



FUNGICIDE & SPOO-KT is a light blue to blue coloured lotion with pleasant odour filled in HDPE bottle.

The excipients used are Polyquaternium 7, Sodium Laureth Sulfate, Cocamide MEA, Cocamidopropyl Betaine, Glycol Distearate, and Sodium Chloride, Triethanol Lauryl Sulphate, Carbomer, Citric Acid, Brilliant Blue.

## **8. Pharmaceutical particulars**

### **8.1. Incompatibilities**

Not applicable

### **8.2. Shelf-life**

Do not use later than date of expiry.

### **8.3. Packaging information**

FUNGICIDE & SPOO-KT is packed in 90 ml bottle.

### **8.4. Storage and handing instructions**

Store below 30°C, Protected from light. Shake well before use. Keep out of reach of children.

*Precaution:* Avoid contact with Eyes. If contact occurs, rinse thoroughly with water, discontinue if signs of irritation develop.

## **9. Patient Counselling Information**

Ask the patients to inform the treating physicians in case of any of the below:

- Have any allergies
- Have kidney or liver problems
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illness
- Are taking any medicines (prescription, over-the-counter, vitamins, or herbal products)

## **10. Details of manufacturer**

Aurochem Laboratories (India) Pvt. Ltd.

Plot No. 8, Palghar Taluka Ind.

Co. Op. Estate Ltd., Boisar Road

Thane - 401404 Taluka: Palghar,

District: Thane-Zone-4

## **11. Details of permission or licence number with date**

Mfg Lic No. KD/326 issued on 11.12.2021.

## **12. Date of revision**

NA

**MARKETED BY**

**TORRENT**  
PHARMA

TORRENT PHARMACEUTICALS LTD.  
**IN/FUNGICIDE & SPOO-KT/JAN-2026/01/PI**