

## **1. NAME OF THE MEDICINAL PRODUCT**

Ketoconazole 20mg/g Shampoo

## **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Ketoconazole 20mg/g.

Excipient with known effect:

Sodium laureth sulfate

For a full list of excipients see section 6.1

## **3 PHARMACEUTICAL FORM**

Shampoo.

Clear, pink solution.

## **4 CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

Prevention and treatment of infections in which the yeast *Malassezia* (previously called *Pityrosporum*) is likely to be involved, such as dandruff, seborrhoeic dermatitis and tinea (pityriasis) versicolor.

### **4.2. Posology and Method of Administration**

**Adolescents and Adults:**

Ketoconazole 20mg/g Shampoo is for use in adolescents and adults.

Shake the bottle well. Wash the hair or affected areas of the skin with Ketoconazole shampoo. Leave in contact for 3-5 minutes before rinsing thoroughly.

\* *Seborrhoeic dermatitis and dandruff:*

Treatment of: Use Ketoconazole 20mg/g Shampoo twice weekly for 2-4 weeks.

Prophylaxis of: Use Ketoconazole 20mg/g Shampoo once every 1-2 weeks.

\* *Tinea (Pityriasis) versicolor:*

Treatment of: Use Ketoconazole 20mg/g Shampoo once daily for a maximum of 5 days.

Prophylaxis of: As patches of pityriasis versicolor become more apparent on exposure to the sun, Ketoconazole 20mg/g Shampoo may be used once daily for a maximum of 3 days in a single treatment course before exposure to sunshine.

#### **Paediatric population:**

The safe and effective use of Ketoconazole 20mg/g Shampoo in infants and children under the age of 12 years has not been established.

### **4.3 Contraindications**

Hypersensitivity to ketoconazole or any of the other ingredients of the preparation.

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

To prevent a rebound effect after stopping prolonged treatment with topical corticosteroids, it is recommended to continue applying the topical corticosteroid together with Ketoconazole 20mg/g Shampoo and to subsequently and gradually withdraw the steroid therapy over a period of 2-3 weeks.

Seborrhoeic dermatitis and dandruff are often associated with increased hair shedding, and this has also been reported, although rarely, with the use of ketoconazole containing shampoos (see Undesirable Effects).

Keep out of the eyes. If the shampoo should get into the eyes, they should be bathed with cold water.

This medicine contains 380 mg sodium laureth sulfate in 1 g. Sodium laureth sulfate may cause local skin reactions (such as stinging or burning sensation) or increase skin reactions caused by other products when applied on the same area.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

None known

#### **4.6 Fertility, pregnancy and lactation**

Since no ketoconazole is detected in plasma following topical administration to the scalp, pregnancy and lactation are not a contra-indication for the use of Ketoconazole 20mg/g Shampoo.

There are no adequate and well-controlled studies in pregnant or lactating women. Data on a limited number of exposed pregnancies indicate no adverse effects of topical ketoconazole on pregnancy or on the health of the foetus/newborn child. Animal studies have shown reproductive toxicity at doses that are not relevant to the topical administration of ketoconazole. No effects on the breastfed newborn/infant are anticipated. See Pharmacokinetic properties, section 5.2.

Plasma concentrations of ketoconazole were not detectable after topical administration of ketoconazole 20mg/g shampoo to the scalp of non-pregnant humans. Plasma levels were detected after topical administration of ketoconazole 20mg/g shampoo on the whole body. There are no known risks associated with the use of ketoconazole 20mg/g shampoo in pregnancy or lactation.

#### **4.7 Effects on ability to drive and use machines**

None known

#### **4.8 Undesirable Effects**

The following table displays ADRs that have been reported with the use of Ketoconazole 20mg/g Shampoo from either clinical trial or post marketing experiences.

The displayed frequency categories use the following convention:

Very common ( $\geq 1/10$ )

Common ( $\geq 1/100$  to  $< 1/10$ )

Uncommon ( $\geq 1/1,000$  to  $< 1/100$ )

Rare ( $\geq 1/10,000$  to  $< 1/1,000$ )

Very rare ( $< 1/10,000$ )

Not known (cannot be estimated from the available clinical trial data).

System Organ Class	Adverse Drug Reactions		
	Frequency Category		
	Uncommon ( $\geq 1/1,000$ to $< 1/100$ )	Rare ( $\geq 1/10,000$ and $< 1/1,000$ )	Not Known
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 Conditions	Application site erythema Application site irritation Application site pruritus Application site reaction	Application site hypersensitivity Application site pustules	

#### 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 the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

## 4.9 Overdose

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 instigated.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Imidazole and triazole derivatives.

ATC Code: D01A C08 (Topical use).

Ketoconazole is an imidazole-dioxolane antimycotic, active against yeasts,

including *Malassezia* and dermatophytes. Its broad spectrum of activity is already well known.

Ketoconazole also has a direct anti-inflammatory action independent from its antifungal activity which may contribute to symptom relief in dandruff and seborrhoeic dermatitis.

## **5.2. Pharmacokinetic Properties**

Ketoconazole does not appear to be appreciably absorbed systemically following topical application of a 20mg/g shampoo to skin. Ketoconazole was not detected in plasma of patients receiving topical application of 20mg/g shampoo 4-10 times weekly for 6 months, or in patients using 20mg/g shampoo 2-3 times weekly for an average of 16 months. Following a single topical application, substantial amounts of the drug were detected in hair 12 hours after application; however only 5% of the applied ketoconazole was detected in hair keratin. Following repeated (twice weekly for 2 months) application, 20% of the applied dose was detected in hair keratin.

## **5.3 Preclinical safety data**

In vitro studies using ketoconazole in a microbial system (i.e., Ames test) have not shown the drug to be mutagenic. In addition, there was no evidence of mutagenicity in any stage of germ cell development in a dominant lethal mutation test in mice who received single oral doses of ketoconazole as high as 80 mg/kg. There was no evidence of carcinogenicity in a long-term feeding study in mice and rats. Hepatotoxicity featured prominently in high dose toxicology studies in animals and occurs in about 1 in 10,000 patients.

# **6 PHARMACEUTICAL PARTICULARS**

## **6.1 List of excipients**

Sodium laureth sulfate  
Disodium laureth sulfosuccinate  
PEG-120 Methyl glucose dioleate  
PEG-7-Glyceryl Cocoate  
Imidurea  
Lauryldimonium hydroxypropyl hydrolysed collagen  
Cocamide DEA  
Sodium hydroxide  
Sodium chloride  
Erythrosine C.I. 45430 (E127)  
Hydrochloric acid concentrated

Purified water

## **6.2 Incompatibilities**

None known

## **6.3 Shelf life**

2 years

## **6.4 Special precautions for storage**

Do not store above 25 °C

## **6.5 Nature and contents of container**

White opaque HDPE bottle with PP closure.  
Pack sizes 60, 80, 100, 120, 125, 150ml (Dandrazol 2% Shampoo).

## **6.6 Special precautions for disposal**

No special instructions

## **7 MARKETING AUTHORISATION HOLDER**

Crescent Pharma Limited  
Key House  
Sarum Hill, Basingstoke  
RG21 8SR  
United Kingdom

## **8 MARKETING AUTHORISATION NUMBER(S)**

PL 20416/0875

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

30/01/2009

## **10 DATE OF REVISION OF THE TEXT**

04/09/2024