PROFESSIONAL INFORMATION

KEZ

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

KEZ 20mg/g shampoo

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 gram of shampoo contains 20 mg ketoconazole.

Excipients with known effect:

Preservative: Imidurea 0,3 % *m/m*.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution.

Clear, pink, coloured shampoo solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

KEZ is indicated for the treatment of:

Infections due to the yeast *Malassezia* (previously called *Pityrosporum*), such as pityriasis versicolor, seborrhoeic dermatitis and pityriasis capitis (dandruff).

4.2 Posology and method of administration

Topical application, for external use only.

Shampoo:

Apply KEZ to the affected areas of the wet skin or the wet hair and rub in lightly. Leave for 3 - 5 minutes before rinsing thoroughly.

Treatment:

Pityriasis versicolor:

Use once daily for a maximum of 5 days.

Seborrhoeic dermatitis and pityriasis capitis (dandruff):

Use twice weekly (every 3 - 4 days) for 2 - 4 weeks.

4.3 Contraindications

Known hypersensitivity to ketoconazole or any of the excipients of KEZ (see section 6.1).

4.4 Special warnings and precautions for use

Avoid contact with the eyes. However, if this happens, rinse the eyes with water.

When KEZ is used immediately after prolonged treatment with topical corticosteroids, irritation may occur (see section 4.8).

To prevent a rebound effect after stopping prolonged topical corticosteroid treatment, the following is recommended:

- continue applying a mild corticosteroid in the morning and apply KEZ in the evening
- subsequently and gradually withdraw the corticosteroid therapy over a 2 - 3 week period.

4.5 Interaction with other medicines and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

KEZ has no influence on the ability to drive or use machines.

4.8 Undesirable effects

Tabulated summary of adverse reactions

System Organ Class	Frequency	Side effects
Infections and Infestations	*Less frequent*	Folliculitis
Immune system disorders	*Less frequent*	Hypersensitivity reactions
Nervous system disorders	*Less frequent*	Dysgeusia
Eye disorders	*Less frequent*	Increased lacrimation, eye irritation
Skin and subcutaneous tissue disorders	*Less frequent*	Dry skin, dryness or oiliness of the hair and scalp, hair discolouration (mainly in patients with chemically damaged hair or grey hair), hair texture abnormal, irritation, skin exfoliation, contact dermatitis, burning sensation, stinging or itching, rash, acne, increase in hair loss (alopecia), angioedema*, urticaria*, seborrheic dermatitis, dandruff, skin disorder
General disorders and administrative site conditions	*Frequency unknown*	Application site erythema, pruritus, skin reaction, application site hypersensitivity pustules

*Post marketing events.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the online service for adverse drug reaction reporting by using either of the following the links: https://www.sahpra.org.za/Publications/Index/8 or http://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-report-form/.

An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

4.9 Overdose

Signs and symptoms

Refer to section 4.8. In overdose, side effects can be precipitated and/or be of increased severity.

Management of overdose

Supportive measures should be carried out in the event of accidental ingestion. Neither emesis nor gastric lavage should be performed in order to prevent aspiration.

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Imidazole and triazole derivatives

ATC code: D01AC08

Pharmacological classification: A 20.2.2 Fungicides

Mechanism of action

Ketoconazole is an imidazole-dioxolane antimycotic having potent antifungal activity against dermatophytes, such as *Trichophyton sp., Epidermophyton sp., Microsporum sp.* and yeasts, such as *Candida sp.* and *Malassezia furfur* (*Pityrosporum ovale*).

5.2 Pharmacokinetic properties

Even after chronic use, the percutaneous absorption of KEZ is negligible as blood levels cannot be detected.

5.3 Preclinical safety data

No further information of relevance available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Foaming base:

Sodium laureth sulphate

Disodium laureth sulphosuccinate

Cocamide DEA

Viscosity regulator:

PEG-120-methyl glucose diolate

Sodium chloride

Refatting agent:

PEG-7-glyceryl cocoate

pH regulator:

Sodium hydroxide

Hydrochloric acid concentrate

Hair conditioner:

Laurdimonium hydroxypropyl

hydrolysed collagen

Colour agent:

Erythrocine

Preservative:

Imidurea 0,3 % *m/m*

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 30 ºC

Keep bottle well closed.

6.5 Nature and contents of container

White, HDPE bottles of 100 ml containing 80 ml of liquid, contained in a printed outer carton.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House

Steenberg Office Park

Silverwood Close

Westlake, 7945

Cape Town, South Africa

8. REGISTRATION NUMBER(S)

A33/20.2.2/0472

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09 May 2002

10. DATE OF REVISION OF THE TEXT

13 April 2023

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