

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 wet skin or 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 the use of machines.

4.8 Undesirable effects

Tabulated summary of adverse reactions

System Organ Class	Frequency	Side effects
Infections and Infestations	<i>Less frequent</i>	Folliculitis
Immune system disorders	<i>Less frequent</i>	Hypersensitivity reactions
Nervous system disorders	<i>Less frequent</i>	Dysgeusia
Eye disorders	<i>Less frequent</i>	Increased lacrimation, eye irritation
Skin and subcutaneous tissue disorders	<i>Less frequent</i>	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	<i>Frequency unknown</i>	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 links: <https://www.sahpra.org.za/Publications/Index/8> or <http://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-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 an 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 sulfosuccinate

Cocamide DEA

Viscosity regulator:

PEG-120 Methyl glucose dioleate

Sodium chloride

Refatting agent:

PEG-7-glyceryl cocoate

pH regulator:

Sodium hydroxide

Hydrochloric acid concentrate

Hair conditioner:

Lauryldimonium hydroxypropyl

hydrolysed collagen

Colour agent:

Erythrosine

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 °C

Keep bottle well closed.

6.5 Nature and contents of container

White, HDPE 100 mL bottle containing 80 mL of liquid, packed 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

A33/20.2.2/0472

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MOZ 2425

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS [S1]

KEZ 20 mg/g shampoo
Ketoconazole

Read all of this leaflet carefully because it contains important information for you

- Keep this leaflet. You may need to read it again.
- Do not share KEZ with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 5 days in the case of pityriasis versicolor and 4 weeks in the case of seborrhoeic dermatitis and pityriasis capitis.

What is in this leaflet

1. What KEZ is and what it is used for
2. What you need to know before you use KEZ
3. How to use KEZ
4. Possible side effects
5. How to store KEZ
6. Contents of the pack and other information

1. What KEZ is and what it is used for

KEZ belongs to a group of medicines called antifungals.

KEZ is used for the treatment of infections of the skin and scalp associated with the fungus *Malassezia* (previously called *Pityrosporum*), such as:

- seborrhoeic dermatitis (a skin disorder affecting the scalp, face, and trunk causing scaly, flaky, itchy, red skin)
- pityriasis capitis (dandruff)
- pityriasis versicolor (a condition causing white to brown patches to develop on parts of the body).

Malassezia fungus is found on everyone's skin, but sometimes it can overgrow and cause problems. KEZ works by killing the fungus and stopping it from coming back.

2. What you need to know before you use KEZ

Do not use KEZ:

- if you are hypersensitive (allergic) to ketoconazole or any of the other ingredients of KEZ (listed in section 6).

Warnings and precautions

Take special care with KEZ:

Avoid contact in the eyes. If this happens, rinse your eyes with water.

If you use KEZ immediately after prolonged treatment with topical corticosteroids (corticosteroid cream), irritation may occur.

To prevent a rebound effect (stop your condition from flaring up) after stopping prolonged topical corticosteroid treatment, the following is recommended:

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

Other medicines and KEZ

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

KEZ is not known to interact with any other medicines.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using KEZ. Safety and efficacy of KEZ during pregnancy and lactation have not been established .

Driving and using machines

KEZ is not likely to affect your ability to drive and use machinery.

3. How to use KEZ

Topical use, for external use only.
Do not share medicines prescribed for you with any other person. Always use KEZ exactly as directed in this leaflet, or as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Shampoo:

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

Treatment:

Pityriasis versicolor:

Use once daily for a maximum of 5 days.

Seborrhoeic dermatitis and pityriasis capitis:

Use twice weekly (every 3 - 4 days) for 2 - 4 weeks.
Regular shampoo should be used on other occasions.

If you have the impression that the effect of KEZ is too strong or too weak, tell your doctor or pharmacist.

If you use more KEZ than you should

In the event that KEZ is accidentally swallowed, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use KEZ

Do not use a double dose to make up for forgotten individual doses.

4. Possible side effects

KEZ can have side effects.
Not all side effects reported for KEZ are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using KEZ, please consult your healthcare provider for advice.

If any of the following happens, stop using KEZ and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- hives (rash or itching)
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to KEZ. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- infection of the hair roots with symptoms such as red, painful, pus-filled swellings on the scalp
- unusual hair loss, shedding or thinning
- dry skin, rash, burning, stinging or itching, shedding of the top layer of skin, inflammation of your skin, dandruff, flaky skin
- acne
- dryness or oiliness of the hair or scalp
- hair discolouration (mainly in patients with chemically damaged hair or grey hair)
- changes in how your hair feels (texture changes)
- dysgeusia (metallic, foul, salty taste in the mouth)
- increased flow of tears and eye irritation.

The following side effects have been reported but the frequency for them to occur is not known:

- redness, irritation or pustules in the area you have applied KEZ.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report any side effects to SAHPRA via the online service for adverse drug reaction reporting by using either of the following links: <https://www.sahpra.org.za/Publications/Index/8> or <http://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/>. By reporting side effects, you can help provide more information on the safety of KEZ. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store KEZ

Store all medicines out of reach of children.

Store at or below 30 °C.

Keep the bottle well closed.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What KEZ contains:

The active ingredient is ketoconazole.

Each 1 g contains 20 mg ketoconazole.

The other ingredients are:

Foaming base: cocamide DEA, disodium laureth sulfosuccinate, sodium laureth sulphate

Viscosity regulator: PEG-120 methyl glucose dioleate, sodium chloride

Refatting agent: PEG-7-glyceryl cocoate

pH regulator: hydrochloric acid concentrate, sodium hydroxide

Hair conditioner: lauryldimonium hydroxypropyl hydrolysed collagen

Colour agent: Erythrosine

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

What KEZ looks like and contents of the pack

A clear, pink, thick solution.

White, HDPE 100 mL bottle containing 80 mL of liquid, packed in a printed outer carton.

Holder of Certificate of Registration

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PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS [S1]

KEZ 20mg/g sjampoe
Ketokonasol

Lees hierdie hele inligtingsblad noukeurig deur, omdat dit belangrike inligting vir u bevat

- Hou hierdie inligtingsblad. Dit mag nodig wees vir u om dit weer lees.
- Moet nie KEZ met enige ander persoon deel nie.
- Vra u gesondheidsorgverskaffer, of apteker, indien u meer inligting of advies benodig.
- U moet 'n dokter besoek, indien u simptome versleg, of nie na 5 dae, in die geval van pityriasis versicolor, of 4 weke, in die geval van seborreiese dermatitis en pityriasis capitis, verbeter nie.

Wat hierdie inligtingsblad bevat

1. Wat KEZ is en waarvoor dit gebruik word
2. Wat u nodig het om te weet, voordat u KEZ gebruik
3. Hoe om KEZ te gebruik
4. Moontlike newe-effekte
5. Hoe om KEZ te bewaar
6. Verpakkingsinhoud en ander inligting

1. Wat KEZ is en waarvoor dit gebruik word

KEZ behoort aan 'n groep medisyne wat swamwerende middels genoem word.

KEZ word gebruik vir die behandeling van vel- en kopvelinfeksies wat verbind word met die swam *Malassezia* (voorheen *Pityrosporum* genoem), soos:

- seborreiese dermatitis ('n velverstoring wat die kopvel, gesig en romp aantas en skubberige, skifferende, jeukerige en rooi vel veroorsaak)
- pityriasis capitis (skiflers)
- pityriasis versicolor ('n toestand wat veroorsaak dat wit tot bruin vlekke op dele van die liggaam ontwikkel).

Malassezia swam word op almal se vel gevind, maar somtyds kan dit oorgroei en probleme veroorsaak. KEZ werk deur die swam uit te wis en te verhoed dat dit terugkeer.

2. Wat u behoort te weet voordat u KEZ gebruik

Moet nie KEZ gebruik:

- indien u hipersensitief (allergies) is vir ketokonasol of enige van die ander bestanddele van KEZ nie (gelys in afdeling 6).

Waarskuwings en voorsorgmaatreëls:

Neem spesiale sorg met KEZ:

Vermyn kontak met die oë. Indien dit gebeur, spoel u oë uit met water.

Irritasie mag voorkom indien u KEZ onmiddellik, na langtermyn behandeling met topikale kortikosteroïde (kortikosteroïedroom), gebruik.

Om 'n terugslag uitwerking te verhoed (verhoed die opflikkering van u toestand), na die langdurige gebruik van topikale kortikosteroïed behandeling, word die volgende aanbeveel:

- hou aan om 'n ligte topikale kortikosteroïed in die oggend aan te wend en wend KEZ saans aan,
- onttrek daarna, geleidelik die kortikosteroïed behandeling oor 'n tydperk van 2 - 3 weke.

Ander medisyne en KEZ

Vertel altyd u gesondheidsorgverskaffer indien u enige ander medisyne neem. (Dit sluit aanvullende of tradisionele medisyne in).

KEZ is nie bekend daarvoor om wisselwerkings met ander medisyne te veroorsaak nie.

Swangerskap, borsvoeding en fertiliteit

Indien u swanger is, of u baba borsvoed, vermoed dat u swanger is, of 'n baba beplan, raadpleeg asseblief u dokter, apteker, of ander gesondheidsorgverskaffer vir advies, voordat u KEZ gebruik. Die veiligheid en doeltreffendheid van KEZ tydens swangerskap en borsvoeding, is nie vasgestel nie.

Bestuur en die hantering van masjinerie:

Dit is onwaarskynlik dat KEZ u vermoë om te bestuur en masjinerie te hanteer, beïnvloed.

3. Hoe om KEZ te gebruik:

Moet nie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie.

Gebruik KEZ altyd presies soos in die inligtingsblad aangedui word, of soos deur u dokter aanbeveel is. U moet u dokter of apteker raadpleeg, indien u onseker is.

Sjampoe:

Wend KEZ aan die aangetaste gedeeltes van nat vel of hare aan en vryf liggies in. LOS aan vir 3 - 5 minute, voordat dit deeglik afgespoel word.

Behandeling:

Pityriasis versicolor:

Gebruik een keer daaglik vir 'n maksimum van 5 dae.

Seborreiese dermatitis en pityriasis capitis:

Gebruik twee maal weekliks (elke 3 - 4 dae), vir 2 - 4 weke.
Normale sjampoe moet op ander geleentheids gebruik word.

Indien u onder die indruk is dat die uitwerking van KEZ té sterk of té swak is, vertel u dokter of apteker.

Indien u meer KEZ gebruik as wat u behoort:

In die geval waar KEZ per abuis ingesluk word, raadpleeg u dokter of apteker. Indien beide nie beskikbaar is nie, kontak u naaste hospitaal of gifbeheersentrum.

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