PATIENT INFORMATION LEAFLET

KEZ

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 health care 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 take/use KEZ

Do not take 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 the wet skin or the 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 accidently 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 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 mL contains 20 mg ketoconazole.

The other ingredients are:

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

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

Refatting agent: PEG-7-glyceryl cocoate

pH regulator: hydrochloric acid concentrate, sodium hydroxide

Hair conditioner: laurdimonium hydroxypropyl hydrolysed collagen

Colour agent: Erythrocine

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

What KEZ looks like and contents of the pack

A clear, pink, thick solution.

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

Holder of Certificate of Registration

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