

PATIENT INFORMATION LEAFLET
KEZ (SOLUTION)

SCHEDULING STATUS:

S1

KEZ 20 mg solution

Ketoconazole

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

KEZ is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use KEZ carefully to get the best results from it.

- 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 used for:

KEZ belongs to a group of medicines called antifungals.

PATIENT INFORMATION LEAFLET

KEZ (SOLUTION)

KEZ is used for the treatment of infections of the skin and scalp associated with the fungus

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).

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 to 3 week period.

Other medicines and KEZ

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

PATIENT INFORMATION LEAFLET**KEZ (SOLUTION)**

When KEZ is used immediately after prolonged treatment with topical corticosteroids, irritation may occur (see Take special care with KEZ).

Pregnancy, breastfeeding and fertility

The safety of KEZ during pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

Driving and using machines

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

3. How to use KEZ:**TOPICAL APPLICATION.****For external use only (do not drink).**

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. Check with your doctor or pharmacist if you are not sure.

Shampoo:

Apply KEZ to the affected areas of the wet skin or the wet hair and rub in lightly. Leave on for 3 to 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 to 4 days) for 2 to 4 weeks.

PATIENT INFORMATION LEAFLET**KEZ (SOLUTION)**

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 centre.

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 health care 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, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.
- Hives (rash or itching).

These are all very serious side effects. If you have them, you may have had a serious reaction to KEZ. You may need serious 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.

PATIENT INFORMATION LEAFLET**KEZ (SOLUTION)**

- Unusual hair loss, shedding or thinning.
- Dry skin, rash, burning, stinging or itching, shedding of the top layer of 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.

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 “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of KEZ.

5. How to store KEZ

Store at or below 25 °C.

Keep the bottle well closed.

KEEP OUT OF REACH OF CHILDREN.

Do not use after the expiry date printed on the label or carton.

Return all unused medicine to your pharmacist.

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