

## PATIENT INFORMATION LEAFLET

### KEZ

#### SCHEDULING STATUS

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#### PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

KEZ (liquid)

#### Please read this leaflet carefully before using KEZ SHAMPOO

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

#### 1. WHAT KEZ CONTAINS

##### *Active ingredient:*

Each 1 gram liquid contains 20 mg ketoconazole.

##### *Inactive ingredients:*

PEG-7 glyceryl cocoate, sodium laureth sulphate, disodium laureth sulphosuccinate, PEG-120 methyl glucose dioleate, cocamide DEA, lauryldimonium hydroxypropyl hydrolysed collagen, sodium hydroxide, sodium chloride, hydrochloric acid concentrate, purified water, erythrosine C.I. 45430 (as colourant).

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

#### 2. WHAT KEZ IS USED FOR

- KEZ shampoo is used to treat infections due to the yeast *Pityrosporum*, such as pityriasis versicolor; tinea versicolor, seborrhoeic dermatitis (a skin disorder affecting the scalp, face, and

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trunk causing scaly, flaky, itchy, red skin) and pityriasis capitis (dandruff).

### 3. BEFORE YOU USE KEZ

#### Do not use KEZ:

- If you are allergic (hypersensitive) to ketoconazole or to any other ingredients (see **WHAT KEZ CONTAINS**).

#### 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 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,
- and subsequently and gradually withdraw the corticosteroid therapy over a 2 to 3 week period.

#### **Pregnancy and breastfeeding:**

The safety of KEZ has not been established during pregnancy and breastfeeding. Consult your doctor before using KEZ if you are pregnant or breastfeeding your baby.

#### **Driving and using machinery:**

KEZ will most likely not make you drowsy or impair your ability to drive and use machinery, but take care if you feel dizzy, tired or drowsy while using KEZ.

#### **Using other medicines with KEZ:**

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There are no known interactions with KEZ and other medicines.

#### 4. HOW TO USE KEZ

##### TOPICAL APPLICATION.

**For external use only (do not drink).**

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 (dandruff):***

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

##### ***Prophylactic (preventing) seborrhoeic dermatitis:***

Use once a week. Regular shampoo should be used on other occasions.

#### 5. POSSIBLE SIDE EFFECTS

KEZ may have side effects. Not all side effects reported for this medicine are included in this leaflet.

**Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.**

Stop using KEZ and seek medical help if you have any of these signs of an allergic reaction:  
hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

***Consult your doctor if any of the following side effects continue or are bothersome:***

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- Dry skin, dryness or oiliness of the hair and scalp, hair discolouration (mainly in patients with chemically damaged hair or grey hair), irritation, skin rash, burning sensation, stinging or itching.
- Hair loss or hair shedding.

**6. STORAGE AND DISPOSAL OF KEZ**

- Store below 25°C. Keep well closed
- Do not remove from the outer carton until required for use
- 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 shampoo in drains and sewerage systems (e.g. toilets)
- KEEP OUT OF REACH OF CHILDREN.