

## KEZ

**SCHEDULING STATUS:**

S1

**PROPRIETARY NAME (AND DOSAGE FORM):**

Kez (liquid)

**COMPOSITION:**

Each 1 gram liquid contains ketoconazole 20 mg.

Preservative: Imidurea 0,3% m/m.

**PHARMACOLOGICAL CLASSIFICATION:**

A: 20.2.2 Fungicides.

**PHARMACOLOGICAL ACTION:**

Ketoconazole is a synthetic imidazole dioxalane derivative having a potent antifungal activity against dermatophytes, such as *Trichophyton sp.*, *Epidermophyton sp.*, *Microsporum sp.* and yeasts, such as *Candida sp.* and *Malassezia furfur (Pityrosporum ovale)*.

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

**INDICATIONS:**

Kez is indicated for the:

Treatment of infections due to the yeast *Pityrosporum*, such as pityriasis versicolor, seborrhoeic dermatitis and pityriasis capitis (dandruff).

Prophylactic treatment of seborrhoeic dermatitis.

**CONTRA-INDICATIONS:**

Individuals who are hypersensitive to any of the ingredients.

**DOSAGE AND DIRECTIONS FOR USE:****TOPICAL APPLICATION.****For external use only.**

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 seborrhoeic dermatitis:

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

**SIDE-EFFECTS AND SPECIAL PRECAUTIONS:**

After topical administration, irritation, dermatitis, or a burning sensation has occurred. Less frequently, mainly in patients with chemically damaged hair or grey hair, hair discolouration has been observed.

Increased hair shedding is often associated with seborrhoeic dermatitis and dandruff, and this has also been reported, though rarely with the use of KEZ.

When KEZ is used immediately after prolonged treatment with topical corticosteroids, 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 lactation*

As safety has not been established, it is not recommended during pregnancy and lactation although KEZ is not absorbed through the skin.

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

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

See "Side-effects and special precautions".

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.

**IDENTIFICATION:**

Clear, pink, thick solution.

**PRESENTATION:**

White, plastic bottles of 100 ml containing 80 ml.

**STORAGE INSTRUCTIONS:**

Store below 25°C. Keep well closed.

KEEP OUT OF REACH OF CHILDREN.

**REGISTRATION NUMBER:**

33/20.2.2/0472

**NAME AND BUSINESS ADDRESS OF APPLICANT:**

Pharma Dynamics (Pty) Ltd.

F02 Grapevine House

Steenberg Office Park

**WESTLAKE**

7945

**DATE OF PUBLICATION OF THIS PACKAGE INSERT:**

28 October 1999

## KEZ

### SKEDULERINGSSTATUS:

S1

### EIENDOMSNAAM (EN DOSEERVORM):

Kez (vloeistof)

### SAMESTELLING:

Elke 1 gram vloeistof bevat ketokonasool 20 mg.

Preserveermiddel: Imidureum 0,3% m/m.

### FARMAKOLOGIESE KLASSIFIKASIE:

A: 20.2.2 Swamdoders.

### FARMAKOLOGIESE WERKING:

Ketokonasool is 'n sintetiese imidasool-dioksolaanderivaat wat potente swamwerende aktiwiteit teen dermatofiete soos bv. *Trichophyton sp.*, *Epidermophyton sp.*, *Microsporum sp.*, en giste soos *Candida sp.*, en *Malassezia furfur (Pityrosporum ovale)*, besit.

Selfs na chroniese gebruik, is perkutane absorpsie van KEZ gering omdat bloedvlakke nie opgespoor kan word nie.

### INDIKASIES:

KEZ is aangedui vir:

Die behandeling van infeksies wat deur die gis *Pityrosporum*, soos bv. pityriasis versicolor, seboreïese dermatitis en pityriasis capitis (skilfers), veroorsaak word.

Profilaktiese behandeling van seboreïese dermatitis.

### KONTRA-INDIKASIES:

Persone wat hipersensitief is teenoor enigeen van die bestanddele.

### DOSIS EN GEBRUIKSAANWYSINGS:

#### TOPIKALE AANWENDING.

#### Slegs vir uitwendige gebruik.

Wend KEZ op die aangetaste gebiede van die nat vel of die nat hare aan, en vryf liggies in. Laat vir 3 tot 5 minute, en spoel dan deeglik af.

### Behandeling:

Pityriasis versicolor:

Gebruik een keer per dag vir 'n maksimum van 5 dae.

Seboreïese dermatitis en pityriasis capitis (skilfers):

Gebruik twee keer per week (elke 3 tot 4 dae) vir 2 tot 4 weke.

Profilaktiese seboreïese dermatitis:

Gebruik een keer per week. Gewone sjampoe behoort op ander geleenthede gebruik te word.

**NEWE-EFFEKTE EN SPESIALE VOORSORGMATREËLS:**

Na topikale aanwending het irritasie, dermatitis, of 'n branderige sensasie al voorgekom. Haar verkleuring is al waargeneem, maar dit het minder dikwels voorgekom en veral in pasiënte met chemies beskadigde hare, of grys hare.

'n Toename in haarverlies word dikwels met seboreïese dermatitis en skilfers geassosieer, en dit is ook al gerapporteer, alhoewel in min gevalle tydens gebruik van KEZ.

Wanneer KEZ onmiddellik na langdurige behandeling met topikale kortikosteroïede gebruik word, mag irritasie voorkom. Om 'n terugslag uitwerking te vermy nadat langdurige topikale kortikosteroïedbehandeling gestaak word, word die volgende aanbeveel:

- gaan voort om 'n ligte topikale kortikosteroïede in die oggend aan te wend, en wend KEZ in die aand aan,
- daarna moet die kortikosteroïedbehandeling geleidelik oor 'n tydperk van 2 tot 3 weke onttrek word.

*Swangerskap en laktasie*

Omdat veiligheid nog nie vasgestel is, word dit nie tydens swangerskap en laktasie aanbeveel, alhoewel KEZ nie deur die vel geabsorbeer word nie.

***Vermy aanraking met die oë. As dit gebeur, spoel oë met water uit.***

**BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:**

Verwys na "Newe-effekte en spesiale voorsorgmaatreëls".

Ondersteunende maatreëls moet toegepas word indien die middel per abuis ingesluk word. Nóg emese, nóg maagspoeling behoort gebruik te word om aspirasie te verhoed nie.

Behandeling is simptomaties en ondersteunend.

**IDENTIFIKASIE:**

Helder, pienk, dik oplossing

**AANBIEDING:**

Wit plastiek bottels van 100 ml wat onderskeidelik 80 ml bevat.

**BERGINGSINSTRUKSIES:**

Bewaar benede 25°C. Hou dig toe.

HOU BUIE BEREIK VAN KINDERS.

**REGISTRASIENOMMER:**

33/20.2.2/0472

**NAAM EN BESIGHEIDSADRES VAN APPLIKANT:**

Pharma Dynamics (Edms) Bpk.

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