

PACKAGE INSERT

hovid

Ketovid Shampoo 2% w/w

VIKET11-PC (MY)

DESCRIPTION

Pink, opaque liquid

COMPOSITION

Ketoconazole (micronized) 2% w/w

ACTIONS AND PHARMACOLOGY

Ketoconazole, a synthetic imidazole dioxolane derivative, has a potent antifungal activity against dermatophytes, such as *Trichophyton* spp., *Epidermophyton* spp., *Microsporum* spp., and yeasts, such as *Candida* spp. and *Malassezia* spp. (*Pityrosporum* spp.). Ketovid Shampoo 2% w/w rapidly relieves scaling and pruritus, which are usually associated with seborrhoeic dermatitis, pityriasis capitis (dandruff) and pityriasis versicolor.

PHARMACOKINETICS

Percutaneous absorption of ketoconazole is negligible as blood levels are not detected, even after chronic use. Systemic effects, therefore, are not expected.

INDICATIONS

Treatment and prophylaxis of infections in which the yeast *Malassezia* (previously called *Pityrosporum*) is involved, such as pityriasis versicolor (localised), seborrhoeic dermatitis and pityriasis capitis (dandruff).

CONTRAINDICATIONS

It is contraindicated in persons who have shown hypersensitivity to the active ingredient or excipients of this formulation.

WARNINGS AND PRECAUTIONS

- Keep out of eyes. Wash the eyes with water if the shampoo contacts the eyes.
- Advise to consult doctor if the scalp has not cleared within 4 weeks.
- Persons who are sensitive to miconazole or other imidazoles may be sensitive to ketoconazole also.
- In patients who have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over a period of 2 to 3 weeks, while using Ketovid Shampoo 2% w/w to prevent any potential rebound effect.
- Increased hair shedding is often associated with seborrhoeic dermatitis and dandruff, and has been rarely reported with the use of Ketovid Shampoo 2% w/w.

DRUG INTERACTIONS

None known

PREGNANCY AND LACTATION

Ketovid Shampoo 2% w/w is not contraindicated during pregnancy and lactation as no ketoconazole is detected in the plasma following topical administration.

MAIN SIDE/ADVERSE EFFECTS

- Topical treatment with Ketovid Shampoo 2% w/w is generally well tolerated.
- A local burning sensation, itching, or contact dermatitis (due to irritation or allergy) may occur on exposed areas.
- Dry skin, dryness or oiliness of the hair and scalp have been reported rarely.
- A discolouration of the hair, mainly in patients with chemically damaged hair or grey hair has been observed.
- There have been very rare reports of eczema and alopecia.

OVERDOSAGE

- Ingestion of Ketovid Shampoo 2% w/w may result in nausea and vomiting due to the detergent. Only supportive measures should be carried out in the event of accidental ingestion.
- In order to avoid aspiration, neither emesis nor gastric lavage should be instigated.

DOSAGE AND ADMINISTRATION

For topical administration.

The affected areas of the skin or the hair should be washed with Ketovid Shampoo, which should be left on the skin for 3 to 5 minutes before rinsing.

Treatment:

- Pityriasis versicolor: once daily for 5 days
- Seborrhoeic dermatitis and pityriasis capitis: twice weekly for 3 to 4 weeks.

Prophylaxis:

- Pityriasis versicolor: once daily for 3 days during a single treatment course before exposure to sunshine.
- Seborrhoeic dermatitis and pityriasis capitis: once every one or two weeks.

Storage : Store below 30°C. Protect from light.
Presentation/Packing : 120 ml in HDPE Bottle

Product Registration Holder / Manufactured by: HOVID Bhd.
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Revision date: January 2017

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