Summary of Product Characteristics

1. Name of the medicinal product

NORBARC CREAM

2. Qualitative and quantitative composition

Ketoconazole 2% w/w (each gram of cream contains 20 mg).

Excipient(s) with known effect:

This medicine contains:

200 mg propylene glycol in each gram cream,

75 mg stearyl alcohol in each gram cream,

20 mg cetyl alcohol in each gram cream.

For a full list of excipients, see 6.1.

3. Pharmaceutical form

Cream

4. Clinical particulars

4.1 Therapeutic indications

For topical application in the treatment of dermatophyte infections of the skin such as tinea corporis, tinea cruris, tinea manus and tinea pedis infections due to Trichophyton spp, Microsporon spp and Epidermophyton spp. NORBARC CREAM is also indicated for the treatment of cutaneous candidosis (including vulvitis), tinea (pityriasis) versicolor and seborrhoeic dermatitis caused by Malassezia (previously called Pityrosporum) spp.

4.2 Posology and method of administration

Ketoconazole cream is for use in adults.

Cutaneous candidosis, tinea corporis, tinea cruris, tinea manus, tinea pedis and tinea (pityriasis) versicolor:

It is recommended that NORBARC CREAM cream be applied once or twice daily to cover the affected and immediate surrounding area.

The usual duration of treatment is: *tinea versicolor* 2–3 weeks, yeast infections 2-3 weeks, *tinea cruris* 2-4 weeks, *tinea corporis* 3–4 weeks, *tinea pedis* 4-6 weeks.

Seborrheic dermatitis:

NORBARC CREAM should be applied to the affected areas once or twice daily.

The usual initial duration of treatment in seborrheic dermatitis is 2 to 4 weeks. Maintenance therapy can be applied intermittently (once weekly) in seborrheic dermatitis.

Treatment should be continued until a few days after the disappearance of all symptoms. The diagnosis should be reconsidered if no clinical improvement is noted after 4 weeks of treatment. General measures in regard to hygiene should be observed to control sources of infection or reinfection.

Seborrhoeic dermatitis is a chronic condition and relapse is highly likely.

Method of administration: Cutaneous administration.

Paediatrics patients

The safety and efficacy of Norbarc Cream in children (17 years of age and younger) has not been established.

4.3 Contraindications

Summary of Product Characteristics

NORBARC CREAM is contra-indicated in patients with a known hypersensitivity to any of the ingredients or to Ketoconazole itself.

4.4 Special warnings and precautions for use

NORBARC CREAM is not for ophthalmic use.

If co administered with a topical corticosteroid, to prevent a rebound effect after stopping a prolonged treatment with topical corticosteroids it is recommended to continue applying a mild topical corticosteroid in the morning and to apply NORBARC CREAM in the evening, and to subsequently and gradually withdraw the topical corticosteroid therapy over a period of 2-3 weeks.

NORBARC cream contains 6000 mg propylene glycol in each 30 g tube, which is equivalent to 200 mg/g.

NORBARC cream contains cetyl alcohol and stearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

There are no adequate and well-controlled studies in pregnant or lactating women. Data on a limited number of exposed pregnancies indicate no adverse effects of topical Ketoconazole on pregnancy or on the health of the foetus/newborn child. Animal studies have shown reproductive toxicity at doses that are not relevant to the topical administration of Ketoconazole.

Plasma concentrations of Ketoconazole are not detectable after topical application of NORBARC CREAM to the skin of non-pregnant humans. (See Pharmacokinetic properties, section 5.2) There are no known risks associated with the use of NORBARC CREAM in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

NORBARC CREAM has no influence on the ability to drive and use machines.

4.8 Undesirable effects

The safety of Ketoconazole cream was evaluated in 1079 subjects who participated in 30 clinical trials. Ketoconazole cream was applied topically to the skin. Based on pooled safety data from these clinical trials, the most commonly reported (≥1% incidence) adverse reactions were (with % incidence): application site pruritus (2%), skin burning sensation (1.9%), and application site erythema (1%).

Including the above-mentioned adverse reactions, the following table displays adverse reactions that have been reported with the use of Ketoconazole cream from either clinical trial or post marketing experiences. The displayed frequency categories use the following convention:

Very common (≥1/10)

Common (≥1/100 to <1/10)

Uncommon (≥1/1,000 to <1/100)

Rare (≥1/10,000 to <1/1,000)

Very rare (<1/10,000)

Summary of Product Characteristics

Not Known (cannot be estimated from the available clinical trial data).

System Organ Class	Adverse Reactions		
	Frequency Category		
	Common (≥1/100 to <1/10)	**Uncommon** (≥1/1,000 to <1/100)	**Not Known**
Immune System Disorders		Hypersensitivity	
Skin and Subcutaneous Tissue Disorders	Skin burning sensation	Bullous eruption Dermatitis contact Rash Skin exfoliation Sticky skin	Urticaria
General Disorders and Administration Site Conditions	Application site erythema Application site pruritus	Application site bleeding Application site discomfort Application site dryness Application site inflammation Application site irritation Application site paresthesia Application site reaction	

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:

Yellow Card Scheme

Website: https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Topical Application

Excessive topical application may lead to erythema, oedema and a burning sensation, which will disappear upon discontinuation of the treatment.

Ingestion

In the event of accidental ingestion, supportive and symptomatic measures should be carried out.

5. Pharmacological properties

6. Pharmaceutical particulars

6.1 List of excipients

Propylene Glycol

Summary of Product Characteristics

Stearyl Alcohol
Cetyl Alcohol
Sorbitan Stearate
Polysorbate 60
Isopropyl Myristate
Sodium Sulphite Anhydrous (E221)
Polysorbate 80
Water purified (Ph. Eur)
6.2 Incompatibilities
Not applicable.
6.3 Shelf life
36 months.
6.4 Special precautions for storage
Do not store above 25°C.
6.5 Nature and contents of container
Tube made of 99.7% aluminum, lined on inner side with heat polymerised epoxyphenol resin with a latex coldseal ring at the end of the tube. The cap is made of 60% polypropylene, 30% calcium carbonate and 10% glyceryl monostearate.
Tube of 30g.
6.6 Special precautions for disposal and other handling
No special requirements
7. Marketing authorizations holder
8. Marketing authorizations number(s)
PL 00242/0107
9. Date of first authorisation/renewal of the authorisation
Date of first authorization: 02 December 1983
Renewed 3 December 2002
10. Date of revision of the text
30 March 2021

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Summary of Product Characteristics

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