Ketoconazole

Core Safety Profile

4.3 Contraindications

NIZORAL 2% Cream is contraindicated in individuals with a known hypersensitivity to any of its ingredients.

4.4 Special warnings and precautions for use

NIZORAL 2% Cream is not for ophthalmic use.

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

NIZORAL 2% Cream in the evening, and to subsequently and gradually withdraw the steroid therapy over a period of 2-3 weeks.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

There are no adequate and well-controlled studies in pregnant or lactating women. Plasma concentrations of ketoconazole are not detectable after topical application of NIZORAL 2% Cream to the skin of non-pregnant humans. There are no known risks associated with the use of NIZORAL 2% Cream in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

The safety of NIZORAL 2% Cream was evaluated in 1079 subjects who participated in 30 clinical trials. NIZORAL 2% Cream was applied topically to the skin. Based on pooled safety data from these clinical trials, the most

commonly reported (≥1% incidence) ADRs were (with % incidence): application site pruritus (2%), skin burning sensation (1.9%), and application site erythema (1%).

Including the above-mentioned adverse drug reactions (ADRs), the following table displays ADRs that have been reported with the use of NIZORAL 2% Cream from either clinical trial or postmarketing 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); and not known (cannot be estimated form the available clinical trial data).

System Organ Class	**Adverse Drug 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	

System Organ Class	Adverse Drug Reactions		
	Frequency Category		
	Common (≥1/100 to <1/10)	**Uncommon** (≥1/1,000 to <1/100)	**Not Known**
		paraesthesia Application site reaction	

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.