

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nizoral™ Dandruff Treatment 2% w/w Shampoo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ketoconazole 2% w/w.

Excipient(s) with known effect:

Sodium lauryl ether sulfate 24% w/w

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Pink viscous shampoo

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

In the prevention and treatment of the scalp conditions dandruff and seborrhoeic dermatitis.

4.2 Posology and method of administration

For topical administration.

Ketoconazole shampoo 2% is for use in adolescents and adults:

Wash affected areas and leave for 3-5 minutes before rinsing. Usually, a palmful of shampoo suffices for one wash.

Treatment:

Dandruff and seborrhoeic dermatitis: Wash hair twice weekly for 2-4 weeks.

Tinea versicolor: Once daily for a maximum of 5 days.

Prophylaxis:

Dandruff and seborrhoeic dermatitis: Use once every 1-2 weeks.

Tinea versicolor: Once daily for a maximum of 3 days before exposure to sunshine.

4.3 Contraindications

Known hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Keep out of the eyes. If the shampoo should get into the eyes, they should be bathed with water.

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have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over a period of 2 to 3 weeks, while using Nizoral Dandruff Treatment 2%w/w Shampoo, to prevent any potential rebound effect.

If the scalp has not cleared within 4 weeks, a doctor or pharmacist should be consulted.

Excipient warnings:

This medicine contains 24% w/w sodium lauryl ether sulfate in each application. Sodium lauryl ether sulfate may cause local skin reactions (such as stinging or burning sensation) or increase skin reactions caused by other products when applied on the same area.

4.5 Interaction with other medicinal products and other forms of interaction

None Known

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. No effects on the breastfed newborn/infant are anticipated. See Pharmacokinetic properties, section 5.2.

Plasma concentrations of ketoconazole were not detectable after topical administration of Nizoral Dandruff Treatment 2% w/w Shampoo to the scalp of non-pregnant humans. Plasma levels were detected after topical administration of Nizoral Dandruff Treatment 2% w/w Shampoo on the whole body. There are no known risks associated with the use of Nizoral Dandruff Treatment 2% w/w Shampoo in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

None likely

4.8 Undesirable effects

The safety of ketoconazole 2% shampoo was evaluated in 2890 subjects who participated in 22 clinical trials. Ketoconazole 2% shampoo was administered topically to the scalp and/or skin. Based on pooled safety data from these clinical trials, there were no ADRs reported with an incidence $\geq 1\%$.

The following table displays ADRs that have been reported with the use of Ketoconazole 2% Shampoo from either clinical trial or postmarketing experiences.

The displayed frequency categories use the following convention:

Very common ($\geq 1/10$)

Common ($\geq 1/100$ to $<1/10$)

Uncommon ($\geq 1/1,000$ to $<1/100$)

Rare ($\geq 1/10,000$ to $<1/1,000$)

Very rare ($<1/10,000$)

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

System Organ Class Adverse Drug Reactions

Frequency Category

Uncommon

($\geq 1/1,000$ to $<1/100$) Rare

($\geq 1/10,000$ and $<1/1,000$) Not Known

Immune System disorders

Hypersensitivity

Nervous System Disorders

Dysgeusia

Infections and Infestations

Folliculitis

Eye Disorders Increased lacrimation Eye irritation

Skin and Subcutaneous Tissue Disorders Alopecia

Dry skin

Hair texture abnormal

Rash

Skin burning sensation

Acne

Dermatitis contact

Skin disorder

Skin exfoliation Angioedema

Urticaria

Hair colour changes

General Disorders and Administration Site Conditions Application site erythema

Application site irritation

Application site pruritus

Application site reaction Application site hypersensitivity

Application site pustules

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation 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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

In the event of accidental ingestion, supportive and symptomatic measures should be carried out. In order to avoid aspiration, neither emesis nor gastric lavage should be instigated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Imidazole and triazole derivatives, ATC code: D01AC08

Ketoconazole is a synthetic imidazole dioxolane antimycotic active against yeasts, including *Malassezia*, and dermatophytes. Its broad spectrum of activity is already well known.

Ketoconazole also has a direct anti-inflammatory action independent from its antifungal activity which may contribute to symptom relief in dandruff and seborrhoeic dermatitis.

5.2 Pharmacokinetic properties

Plasma concentrations of ketoconazole were not detectable after topical administration of Nizoral Dandruff Treatment 2% w/w Shampoo on the scalp. Plasma levels were detected after topical administration of Nizoral Dandruff Treatment 2% w/w Shampoo on the whole body.

5.3 Preclinical safety data

Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium lauryl ether sulfate
Disodium monolauryl ether sulphosuccinate
Coconut fatty acid diethanolamide
Laurdimonium hydrolysed animal collagen
Macrogol 120 methyl glucose dioleate
Sodium chloride
Concentrated hydrochloric acid
Imidurea
Sodium hydroxide
Erythrosine sodium (E127)
Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 25°C

6.5 Nature and contents of container

High-density polyethylene bottle containing 60ml, 100ml or 120ml Nizoral Dandruff Treatment 2% w/w Shampoo

Not all pack sizes may be marketed

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Ltd.,
Linthwaite, Huddersfield,
HD7 5QH, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 00240/0452

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10/12/2010

10 DATE OF REVISION OF THE TEXT

17/08/2023