New Zealand Data Sheet

1. PRODUCT NAME

Sebizole ® 2% w/w Shampoo

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ketoconazole 2% w/w (each mL contains 20.6 mg of ketoconazole).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Sebizole 2% w/w Shampoo is a clear, pink coloured, viscous liquid with a fragrant smell.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Topical treatment of severe seborrhoeic dermatitis and severe dandruff of the scalp in adults.

For both conditions, Sebizole Shampoo provides only temporary relief during the period of its use. Both conditions relapse soon after discontinuation of treatment. The relapse rate for seborrhoeic dermatitis is not known, but for dandruff it is high within a short time after cessation of treatment.

4.2. Dose and method of administration

Dose

Adults

The use of unnecessarily large quantities of Sebizole Shampoo during treatment should be avoided.

The duration of treatment should be limited to twice weekly for no longer than four weeks at any one time. An interval of at least four weeks should be allowed between consecutive courses.

Method of Administration

Topical administration.
Sebizole Shampoo should be applied to the wet scalp, worked into a lather and left on for three to five minutes before rinsing thoroughly with water.

4.3. Contraindications

Hypersensitivity to ketoconazole or to any of the excipients listed in section 6.1.

4.4. Special warnings and precautions for use

Irritation may occur when Sebizole Shampoo is used immediately after prolonged treatment with topical corticosteroids on the same area. Therefore, it is recommended to wait about two weeks after stopping treatment with topical corticosteroids before using Sebizole Shampoo.

If a reaction suggesting sensitivity or chemical irritation should occur, use of Sebizole Shampoo should be discontinued.

Seborrhoeic dermatitis and dandruff are often associated with increased hair shedding, and this has also been reported, although rarely, with the use of ketoconazole 2% w/w shampoo.

Safety of use beyond four weeks has not been adequately established.

Avoid contact with the eyes. If the shampoo should get into the eyes, they should be bathed with cold water.

4.5. Interaction with other medicines 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. There are no known risks associated with the use of ketoconazole 2% shampoo in pregnancy or lactation.

Pregnancy

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.

Breast-feeding

Plasma concentrations of ketoconazole were not detectable after topical administration of ketoconazole 2% shampoo to the scalp of non-pregnant humans. See section 5.2. No effects on the breastfed newborn/infant are anticipated.

Fertility

Animal studies have shown reproductive toxicity at doses that are not relevant to the topical administration of ketoconazole.

4.7. Effects on ability to drive and use machines

Not relevant.

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 ≥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 (≥ 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), Not known (cannot be estimated form the available clinical trial data).

System Organ Class	**Adverse Drug Reactions**		
	Frequency Category		
	Uncommon (≥1/1,000 to <1/100)	**Rare** (≥1/10,000 and <1/1,000)	**Not Known**
Immune System disorders		Hypersensitvity	
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 medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected reactions https://nzphvc.otago.ac.nz/reporting/

4.9. Overdose

Symptoms

Oral ingestion is usually followed by nausea and vomiting due to the detergent.

Treatment

In the event of accidental ingestion, only supportive measures should be employed. To avoid aspiration, neither emesis nor gastric lavage should be performed.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

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

Mechanism of action

Ketoconazole is a broad-spectrum synthetic antifungal agent which inhibits the growth of the following common dermatophytes and yeasts by altering the permeability of the cell membrane.
Dermatophytes: *Trichophyton rubrum, T mentagrophytes, T tonsurans, Microsporum canis, M audouini, M gypseum* and *Epidermophyton floccosum*.
Yeasts: *Candida albicans, C tropicalis, Pityrosporum ovale (Malassezia ovale)* and *P orbiculare (M furfur)*.
Development of resistance to ketoconazole has not been reported.

In vitro studies suggest that ketoconazole impairs the synthesis of ergosterol, which is a vital component of fungal cell membranes. The mechanism of the therapeutic effect in seborrhoeic dermatitis and dandruff has not been established. It is postulated that the therapeutic effect of ketoconazole in dandruff may be due to the reduction in number of *P ovale*, but this has not been proven.

5.2. Pharmacokinetic properties

Plasma concentrations of ketoconazole were not detectable after topical administration of ketoconazole 2% shampoo on the scalp. Plasma levels were detected after topical administration of ketoconazole 2% 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 laureth sulfate, cocamide diolamine, sodium lauril sarcosinate, polyethylene glycol distearate, hydrochloric acid, diazolidinyl urea, Herb Flower fragrance, erythrosine sodium, and purified water.

6.2. Incompatibilities

In the absence of compatibility studies, this medicine must not be mixed with other medicines.

6.3. Shelf life

36 months

6.4. Special precautions for storage

Store at or below 25°C. Protect from light.

6.5. Nature and contents of container

Plastic bottles of 100 mL and 200 mL.
Not all pack sizes may be marketed.

6.6. Special precautions for disposal and other handling

No special requirements for disposal.

7. MEDICINE SCHEDULE

Pharmacy only medicine

8. SPONSOR

Douglas Pharmaceuticals Ltd
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Auckland 0651
New Zealand
Phone: (09) 835 0660

9. DATE OF FIRST APPROVAL

17 September 1998

10. DATE OF REVISION OF THE TEXT

08 March 2018

Summary table of changes

Section Changed	Summary of new information
All	Revised to reflect SPC format
4.6, 4.8, 5.2, 5.3	Information in line with the Source document