PROFESSIONAL INFORMATION

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1. NAME OF THE MEDICINE

SELSUN 2,5 %

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 ml aqueous suspension contains:

Selenium sulfide 2,5 g

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

SELSUN 2,5 % is an orange suspension with a distinctive perfume.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

SELSUN 2,5 % is indicated in the treatment of common dandruff and mild and moderately severe cases of seborrhoeic dermatitis of the scalp. It has been found to be highly effective in controlling chronic seborrhoeic scalp conditions. SELSUN 2,5 % is also effective in the treatment of pityriasis versicolor (tinea versicolor).

4.2 Posology and method of administration

For the treatment of dandruff or seborrhoeic dermatitis of the scalp:

1. Shake before using.
2. Massage about 5 to 10 ml of SELSUN 2,5 % suspension into the wet scalp

with warm water, until you get a rich, creamy lather.

3. Allow lather to remain on the scalp for 2 to 3 minutes.
4. Rinse the scalp thoroughly.
5. Repeat application and rinse thoroughly.
6. After treatment, wash hands.

For the usual case, two applications each week for two weeks will afford control. After this, the SELSUN 2,5 % suspension may be used at less frequent intervals – weekly, biweekly or even every 3 to 4 weeks in some cases. SELSUN 2,5 % suspension should not be applied more frequently than required to maintain control.

For the treatment of pityriasis versicolor:

1. Shake well before using.
2. Apply SELSUN 2,5 % to the whole body, avoiding contact with eyes and mucous surfaces. Allow to remain for 10 minutes. Rinse well.
3. Repeat procedure daily for a total of 7 applications.

Additional courses of treatment should be employed only in cases of persistence or recurrence of infection.

4.3 Contraindications

Hypersensitivity to selenium sulfide or any of the other ingredients of SELSUN 2,5 %. SELSUN 2,5 % should not be applied to inflamed or weeping skin and should not be allowed to get into the eyes. If this happens, rinse thoroughly with water.

4.4 Special warnings and precautions for use

Gold, silver and other metallic jewellery should be removed prior to use, since discolouration of the jewellery may be caused.

For external use only. Keep out of eyes; if SELSUN 2,5 % gets into eyes, wash thoroughly with cold water.

Do not leave the shampoo in contact with the hair or skin for more than the recommended duration as irritation, burning sensation or blistering may occur and do not use more often than recommended.

Cutaneous sensitisation of the scalp or adjacent skin has been reported. Should hypersensitivity reactions occur, use of SELSUN 2,5 % suspension should be discontinued. Chemical conjunctivitis may result if the preparation enters the eyes.

Application of SELSUN 2,5 % suspension to an acutely inflamed scalp may result in percutaneous absorption with the production of systemic toxic effects. SELSUN 2,5 % suspension should not be used when acute inflammation is present.

Oiliness of the hair may increase following use of the aqueous suspension. Yellow or orange discolouration of grey or white hair may occur following use of SELSUN 2,5 % suspension but can usually be avoided by thorough, careful rinsing of the hair after treatment.

SELSUN 2,5 % suspension should be rinsed (five minutes under cool, running water)

from the hair before dyeing, tinting or permanent waving.

When SELSUN 2,5 % suspension is applied to the body for treatment of pityriasis versicolor, care should be taken to avoid contact with the eyes, the genital regions and other mucous surfaces.

Prolonged contact with the skin may cause irritation and dermatitis. It is important to rinse thoroughly after use. If irritation occurs, discontinue use of SELSUN 2,5 % and consult your medical practitioner.

Photosensitivity has seldom been reported.

KEEP OUT OF REACH OF CHILDREN.

4.5 Interaction with other medicines and other forms of interaction

SELSUN 2,5 % should be thoroughly rinsed from the hair before dyeing, tinting, or permanent waving the hair. It should not be applied for a period of two days before or after any of these procedures.

4.6 Fertility, pregnancy and lactation

The safety of this preparation in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Application to the skin or scalp may produce irritation or sensitisation, sometimes described as a burning sensation. Blistering can occur.

Oiliness of the hair may increase following use of SELSUN 2,5 % suspension.

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 providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form" found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

Selenium sulfide is extremely insoluble. Oral ingestion is usually followed by nausea and vomiting due to the detergent. When swallowed, selenium sulfide could be highly toxic. Symptoms include a garlic odour in the breath, loss of appetite, vomiting and anemia.

To treat accidental oral ingestion of SELSUN 2,5 % induce vomiting. General supportive measures must be instituted, and a purgative given to hasten elimination, e.g. give a saline purgative (such as Sodium Sulphate 30 g in 250 ml of water), to promote peristalsis. Urinary excretion may be increased by ascorbic acid (Vitamin C) given by mouth. Further treatment should be symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 13.1 Antiseptics, disinfectants and cleansing agents.

Selenium sulfide acts as an anti-seborrhoeic agent.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

No additional preclinical information, relevant to the indication, is presented.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Bentonite, titanium dioxide, glyceryl monoricinoleate S (Emulsol GMR), citric acid monohydrate, monoethanolamine lauryl sulphate, alkyl (12-14) dimethylbetaine, sodium dihydrogen phosphate dehydrate, perfume LC 01618 MOD 346, sodium chloride, sodium hydroxide for pH adjustment, purified water.

6.2 Incompatibilities

None known.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Store at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

High density polyethylene bottles of 50 ml and 100 ml fitted with white polypropylene caps.

6.6 Special precautions for disposal

None.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Mentholatum South Africa (Pty) Ltd

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Steenberg Office Park

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7945

8 REGISTRATION NUMBER

G1410 (Act 101/1965)

9 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

21 June 2013

10 DATE OF REVISION OF THE TEXT

30 October 2023