Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Selsun Shampoo 2.5% w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100ml of suspension contains 2.5 g (2.5% w/v) of Selenium disulphide Ph. Eur.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Shampoo.
Beige to pale yellow to pale orange uniform suspension; free from large particles.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Simple Dandruff and seborrhoeic dematitis of the scalp.

4.2 Posology and method of administration

Apply topically to the scalp.

Adults and the elderly:

After thoroughly wetting the hair massage Selsun in to form a lather. Rinse after 2 to 3 minutes. Usage should be twice a week for the first tow weeks and then once a week for the next two weeks to control the condition. After this initial course of treatment Selsun should not be used more often than necessary.

Children aged 5-14 years:

As for adults.

Children under 5 years of age:

Not recommended.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

Acute, severe inflammation of the skin.

4.4 Special warnings and precautions for use

Selsun is meant for external application only.
Selsun is not to be ingested. In the event of accidental ingestion, seek immediate medical advice.
This shampoo is an irritant to the eyes. It should therefore be kept away from the eyes.
If the shampoo comes in contact with the eyes, they should rinse thoroughly with cold water.
Exposure of Selsun to eyes may result in ocular injuries such as corneal abrasion (see section 4.8).
Selsun must not be left in contact with the hair or skin for more than the recommended duration as irritation, burning sensation or blistering may occur.
Selsun is not to be used more often than recommended (see section 4.2).

Selsun must not be applied to or on infected or broken skin as this may cause systemic absorption of the selenium sulfide
Gold, silver and other metallic jewellery should be removed prior to use, since discolouration may be caused.

4.5 Interaction with other medicinal products and other forms of interactions

If the hair has been damaged by chemical substances (like dyeing or bleaching products or as a result of a permanent wave or relaxing treatment) or if the hair is grey or white, discoloration of the hair may occur. In order to avoid discoloration of the hair it must be thoroughly rinsed immediately after use.
Selsun should not be applied for a period of two days before or after any of these procedures.
Gold, silver and other metallic jewelry should be removed prior to use of Selsun, since discolouration of the metals may occur.

4.6 Fertility, pregnancy and lactation

No effects during pregnancy are anticipated. Selsun 2.5% can be used during pregnancy.
No effects on the breastfed newborn/infant are inticipated. However, around the breast Selsun 2.5% should not be used. The infant should not be in contact with treated skin areas.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

The following CIOMS frequency rating is used, when applicable: Very common ≥ 10%; Common ≥ 1 and < 10%; Uncommon ≥ 0.1 and < 1%; Rare ≥ 0.01 and < 0.1%; Very rare < 0.01%; Not known (cannot be estimated from available data).

Immune system disorder:
Rare: Hypersensitivity, rash and urticaria.

Skin and subcutaneous tissue disorders:
Frequency unknown: Irritation and sensitization, sometimes described as a burning sensation. Blistering can occur, especially if the shampoo is kept in contact with hair or skin for longer than the recommended duration. Frequency unknown: Alopecia can occur.
Frequency unknown: Diffuse, transient hair loss was reported following the use of medicinal products containing selenium sulphide.
Frequency unknown: Hair colour changes may occur; this can be avoided or minimized by thorough washing of the hair after treatment.
Frequency unknown: Via stimulation of skin and subcutaneous tissue disorders secretion from the sebaceous glands and inhibition of lipolysis of triglycerides medicinal products containing selenium sulphide can lead to greasy hair.
Frequency unknown: Seborrhea (oiliness of hair and scalp) or application site dryness may occur.

Eye Disorders:
Not known: Eye irritation; Corneal abrasion* (see section 4.4)
* eye pain, hyperemia and transient blindness

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 HPRA Pharmacovigilance.
Website: www.hpra.ie

4.9 Overdose

If ingested, vomiting should be provoked and general supportive measures given.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Selenium sulphide appears to have a cytostatic effect on cells of the epidermis and follicular epithelium, thus reducing corneocyte production. Selsun acts as an antiseborrhoeic agent which effectively controls itching and scaling dandruff. It has activity against certain dermatophytes including *Pityrosporum orbiculare*, the organism causing pityriasis versicolor (tinea versicolor).

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
Citric acid monohydrate
Sodium dihydrogen phosphate dihydrate
Glyeryl monoricinoleate S
Monoethanolamine lauryl sulphate
Empigen BB
Perfume LC 01618 MOD
Sodium chloride
Sodium hydroxide
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25ºC

6.5 Nature and contents of container

High density polyethylene bottles fitted with wadless caps, containing 50, 100 or 150 ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Opella Healthcare France SAS T/A Sanofi
82 Avenue Raspail
94250 Gentilly
France

8 MARKETING AUTHORISATION NUMBER

PA23180/013/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1983

Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

December 2021