

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Suleo-M 0.5% w/v Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The lotion contains 0.5% w/v Malathion.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Solution

A clear colourless solution with a characteristic alcoholic and citrus odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of infestation of hair by pediculosis capitis (head lice)

4.2 Posology and method of administration

Topical

Adults, children 6 months of age and over and the elderly:

Rub the lotion gently into the scalp until all hair and scalp is thoroughly moistened. Allow the hair to dry naturally in a well ventilated room. Do not use hair dryer or other artificial heat. Live lice will be eradicated after a minimum treatment period of two hours. However, the lotion should be left on the head for a further period of 8-10 hours to ensure that all lice eggs are totally eradicated. Shampoo in normal manner. Rinse and comb the hair while wet to remove the dead lice.

In the event of early re-infestation, Suleo-M Lotion may be applied again provided 7 days have elapsed since the first application.

Residual protective effect is variable and of short duration and should not be relied upon.

4.3 Contraindications

1. Known hypersensitivity to active constituents
2. Not to be used on infants less than six months old except on medical advice

4.4 Special warnings and precautions for use

1. The eyes should be well protected during the application and washing of hair
2. Persons applying this product should wear rubber gloves so that their continued direct contact is avoided.
3. All members of the household of the patients should be treated, preferably simultaneously.
4. The source of infestation should be sought and treated.

5. This product is poisonous if ingested. If accidentally swallowed, contact your local doctor or hospital immediately.
6. Prolonged continued application should be avoided. It should not be used more than once a week and for not more than three consecutive weeks.
7. Keep out of reach of children.
8. Children under the age of 6 months should only be treated under medical supervision.
9. The lotion should not be applied to damaged skin except after medical consultation.
10. Suleo-M Lotion contains isopropyl alcohol, which may cause wheezing in asthmatic people or cause stinging or inflammation of the skin in people with severe eczema. In either case, it may be more appropriate to use a liquid, which does not contain isopropyl alcohol. Some people with normal skin may also experience stinging and inflammation of the skin, which in a minority of cases may be severe. In such cases use of a liquid may be preferred.
11. Suleo-M Lotion contains alcohol, which is flammable, and special care must be taken when applying to and drying the hair. Do not expose the lotion or wet hair to any naked flames such as open coal, gas or electric fires, or to any lighted objects (e.g. matches, cigarettes or lighters). After application of the lotion, the hair must be allowed to dry naturally and should not in any way be covered or exposed to artificial heat. Treatment should be carried out in a well ventilated room to avoid any discomfort from the alcohol fumes. Ensure that hair has dried before going to bed.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Pregnancy and lactation

No known effects in pregnancy and lactation. However, as with all medicines, use with caution.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Very rarely skin irritation has been reported with malathion products.

4.9 Overdose

In the event of deliberate or accidental ingestion, empty stomach contents by gastric lavage and keep patient warm. In the event of massive ingestion, atropine in doses of 1 or 2mg intravenously may be required to counteract cholinesterase inhibition.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Suleo-M Lotion contains malathion, a widely used organophosphorous insecticide which is active by cholinesterase inhibition. It is effective against a wide range of insects but is one of the least toxic organophosphorous insecticides since it is rapidly detoxified by plasma carboxylesterases.

5.2 Pharmacokinetic properties

Suleo-M Lotion is applied topically to the affected area.

5.3 Preclinical safety data

None stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isopropyl alcohol
D-Limonene 17449
Terpineol 17449
Shellsol T
Citric Acid
Perfume-Loxol P6160 Daniel

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original container.

6.5 Nature and contents of container

Cartoned, clear or amber glass bottles with low density polyethylene caps and high density polyethylene sprinkler inserts containing either 50, 55, 160, 200 or 210ml of product.

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

Seton Products Limited
Tubiton House
Oldham
OL1 3HS
England

8 MARKETING AUTHORISATION NUMBER

PA 0618/018/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 July 1993

Date of last renewal: 13 July 2003