

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Full Marks Lotion 0.2% w/v Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Phenothrin 0.2 % w/v

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution.

Clear, colourless solution having a pleasant herbal, alcoholic aroma.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of head and pubic hair lice infestations

4.2 Posology and method of administration

For topical external use only

Adults, the elderly and children aged 6 months and above:

The source of the infestation should be sought and treated.

Family members and close contacts should be inspected, and if found to be infected, treated simultaneously.

For head lice

1. Sprinkle the lotion on the hair and rub gently onto the head until the entire scalp is moistened. Pay special attention to the back of the neck and the area behind the ears.
2. Allow to dry naturally. Use no heat.
3. The hair may be washed with normal shampoo 2 hours after application.
4. While the hair is still wet, comb with an ordinary comb. The fine-toothed Seton comb can then be used to remove the dead or dying lice and eggs.

Treatment should be repeated after 7 days.

For pubic lice

Application and dosage etc are as for the head. Apply the lotion to the pubic hair and hair between the legs and around the anus. Allow to dry naturally, using no heat.

Treatment should be repeated after 7 days.

Children under 6 months:

Under medical supervision only.

4.3 Contraindications

A history of sensitivity to pyrethroid insecticides

4.4 Special warnings and precautions for use

Contains flammable alcohol. Apply and dry with care. Avoid naked flames and lighted objects. Do not expose to artificial heat (eg electric hairdryers). Dry in a well ventilated room. Do not cover the head before the lotion has dried completely. Ensure that the hair has dried before retiring to bed.

Children under 6 months should only be treated under medical supervision.

Avoid contact with the eyes. The eyes should be well protected during the application and washing of the hair.

When Full Marks Lotion is used by a school nurse or other health officer in the mass treatment of large numbers of children, it is advisable that protective plastic or rubber gloves be worn.

Full Marks Lotion contains isopropanol, which may cause wheezing in asthmatic patients or cause inflammation of the skin in patients with severe eczema. If such effects are apparent, patients should use a shampoo formulation.

Do not use on broken or secondarily infected skin.

Continued prolonged treatment with this product should be avoided. It should not be used more than once a week, and for not more than three consecutive weeks.

This treatment may affect permed, pre-rinsed, coloured or bleached hair. If your hair has been permed, pre-rinsed, coloured or bleached, it is advisable to carry out a strand test, testing a small section of hair, before using this product on the whole head.

The lotion should not be applied to damaged skin except after medical consultation.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Pregnancy and lactation

There are no known effects in human pregnancy and lactation. However, as with all drugs, Full Marks Lotion should be used with caution in pregnant or lactating women.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Some patients may experience stinging or inflammation of the skin due to the alcohol content of the lotion.

Use of Full Marks Lotion may exacerbate asthma or eczema.

4.9 Overdose

In the event of deliberate or accidental ingestion, as for ethyl alcohol, empty the stomach contents by gastric lavage and treat symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Phenothrin

ATC code: P03AC03

Phenothrin is a synthetic pyrethroid insecticide, highly effective against human lice but with an exceptionally low mammalian toxicity.

5.2 Pharmacokinetic properties

Full Marks Lotion is applied topically to the affected area. A pharmacokinetic study has shown absorption of the active constituent is negligible.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isopropyl alcohol

Purified water

Herbal green bouquet P15312

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 30°C. Keep the bottle in the outer carton.

6.5 Nature and contents of container

50 ml, 55 ml, 100ml, 110ml, 160 ml, 200 ml: cartoned, clear or amber type III glass bottle with polyethylene caps and polyethylene sprinkler inserts.

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

Avoid naked flames or lighted objects. Do not use artificial heat (e.g. electric hair dryers). When empty dispose of safely as normal household waste.

7 MARKETING AUTHORISATION HOLDER

SSL International Plc
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Trafford Park
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UK

8 MARKETING AUTHORISATION NUMBER

PA 1138/005/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15 April 1996

Date of last renewal: 15 April 2006

10 DATE OF REVISION OF THE TEXT

June 2009