

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Prioderm 1% w/w Cream Shampoo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Malathion 1.0% w/w

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Shampoo

A pale yellow to orange coloured cream shampoo.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of pediculosis capitis and pediculosis pubis.

4.2 Posology and method of administration

Topical

Apply to wet hair, rub in well. After 5 minutes, rinse and repeat to produce a rich lather. After a final rinse, fine-tooth comb the hair before drying. Repeat twice a three day intervals.

4.3 Contraindications

None.

4.4 Special warnings and precautions for use

For external use only.

If recovery has not occurred, the patient should consult his doctor.

Continued prolonged treatment with this product should be avoided. It should not be used for more than 3 times at 3 day intervals, and then not repeated within a 3 week period.

Children under the age of six months should be treated under medical supervision.

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.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Prioderm Cream Shampoo is not known to have any effect on fertility, pregnancy and lactation. Its use in pregnant or lactating women is not recommended unless there is an overriding need.

4.7 Effects on ability to drive and use machines

None Known.

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 and keep patient warm. In the event of massive ingestion, atropine and pralidoxime may be required to counteract cholinesterase inhibition.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Malathion
ATC code: P03AX03.

Prioderm Cream Shampoo contains malathion, a widely used organophosphorus insecticide which is active by cholinesterase inhibition. It is effective against a wide range of insects, but is one of the least toxic organophosphorus insecticides since it is rapidly detoxified by plasma carboxylesterases.

5.2 Pharmacokinetic properties

Prioderm Cream Shampoo contains malathion, and organophosphorus insecticide which is relatively poorly absorbed from the scalp.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium laurilsulfate paste
 Cetostearyl alcohol
 Lauric diethanolamide
 Ethoxylated lanolin (50%)
 Methyl Parahydroxybenzoate (E218)
 Propyl Parahydroxybenzoate (E216)
 Hydrochloric acid (pH adjuster)
 Citric acid (anhydrous)

Dibasic sodium phosphate
Sunset yellow (E110)
Sodium edetate
Perfume M&B 1658
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf Life

18 months

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Cartoned, internally lacquered aluminium tube with polyethylene caps containing 40 g 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
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8 MARKETING AUTHORISATION NUMBER

PA 0618/016/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28 July 1975

Date of last renewal: 23 July 2005

10 DATE OF REVISION OF THE TEXT

April 2007