

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Malathion Lotion

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Malathion 0.5 % w/v.

*For a full list of excipients, see section 6.1.*

#### 3 PHARMACEUTICAL FORM

Cutaneous solution.

Clear, colourless alcoholic cutaneous solution.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

For the treatment of lice infestation of scalp or body hair. For the treatment of scabies.

This product is intended for treatment only and not prevention of lice and scabies.

##### 4.2 Posology and method of administration

###### For head lice

Apply to the hair, rub gently into scalp and allow to dry naturally. As all lice and eggs will have to be eliminated the hair may be shampooed after 2 hours. The hair may be fine tooth-combed before drying.

###### For pubic lice

As for lice, applying the lotion to the pubic hair and the hair between the legs and around the anus.

###### For scabies

Use cotton wool to apply lotion to all parts of the body except face and scalp, rub in well, allow to dry naturally. Do not bathe until 12 hours after treatment.

##### 4.3 Contraindications

Known hypersensitivity to active constituents.

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 the 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 patient 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 applications should be avoided.

7. Keep out of the reach of children.
8. Children under the age of 6 months should only be treated under medical supervision.
9. It should not be applied to damaged skin except after medical consultation.
10. Malathion Lotion contains isopropyl alcohol which may cause wheezing in asthmatic patients or cause stinging or inflammation of the skin in patients with severe eczema.
11. Malathion contains alcohol which is flammable. Special care must be taken when applying to and drying 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. After application of the lotion, the hair must be allowed to dry naturally and should not 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 the hair is dried before going to bed.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

None stated.

#### **4.6 Pregnancy and lactation**

There are no known adverse effects of Malathion Lotion in human pregnancy and lactation. However, as with all drugs it should be used with caution in pregnant and 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.

#### **4.9 Overdose**

In the event of deliberate or accidental ingestion, empty stomach contents by gastric lavage and keep warm. In the event of massive ingestion, atropine and pralidoxime may be required to counteract cholinesterase inhibition.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Malathion 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**

Malathion Lotion is applied topically to the affected area.

#### **5.3 Preclinical safety data**

None stated.

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Golden delicious perfume P15498

Isopropyl myristate  
Isopropyl alcohol

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf Life**

2 years.

## **6.4 Special precautions for storage**

Do not store above 25°C.

## **6.5 Nature and contents of container**

Cartoned clear glass bottles with a polyethylene cap and polythene sprinkler insert containing 50, 55, 110, 160 and 200 ml of product.

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**

Seton Products Ltd,  
Tubiton House,  
Oldham, OL1 3HS,  
England

## **8 MARKETING AUTHORISATION NUMBER**

PA 0618/016/002

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 07 March 1977

Date of last renewal: 07 March 2007

## **10 DATE OF REVISION OF THE TEXT**

March 2008