

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Suleo-C Lotion

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Carbaryl 0.5% w/v

*For excipients, see 6.1.*

#### 3 PHARMACEUTICAL FORM

Cutaneous solution

Suleo-C Lotion is a pale straw coloured liquid with a herbal aroma.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

For the treatment of infestation of hair, pediculosis capitis or pubis.

##### 4.2 Posology and method of administration

Topical

Apply to hair, rub gently into scalp, and allow to dry naturally. As all lice and eggs will have been eliminated, the hair may be shampooed after 2 hours. If a residual effect is desired, shampoo after 12 hours. The hair may be fine tooth-combed before drying.

Continued prolonged treatment with this product should be avoided. It should not be used more than once a week, and for no longer than three consecutive weeks.

##### 4.3 Contraindications

None

##### 4.4 Special warnings and precautions for use

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

Persons applying this product should wear rubber gloves so that their continued direct contact is avoided.

Should a member of your family need treatment, check other family members for live lice and treat only if infestation is found.

The source of the infestation should be sought and treated.

This product is poisonous if ingested. If accidentally swallowed contact your local doctor or hospital immediately.

Prolonged continued applications should be avoided.

Keep out of reach of children.

Children under the age of 6 months should only be treated under medical supervision.

Avoid exposure to open flame, electric fires, dryers etc, whilst using the product.

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

None stated.

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

None stated.

#### **4.7 Effects on ability to drive and use machines**

None stated.

#### **4.8 Undesirable effects**

Suleo-C Lotion contains isopropyl alcohol which may cause wheezing in asthmatic patients or cause stinging or inflammation of the skin in patients with severe eczema.

The feeding of carbaryl to rats and mice throughout life led to an increased incidence of benign and malignant tumours only at very high doses. However, a range of in vivo and in vitro mutagenicity tests have indicated that carbaryl is not genotoxic. These findings suggest that use of carbaryl to treat louse infestations is unlikely to pose a significant cancer risk in humans.

#### **4.9 Overdose**

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

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

The action of carbamates is to inhibit the acetylcholinesterase present at the synaptic junctions within the insect's nervous system.

#### **5.2 Pharmacokinetic properties**

Suleo-C Lotion is for external use only

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

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Surtic P15413 perfume  
Isopropyl myrisate  
Isopropyl alcohol

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf Life**

24 months

### **6.4 Special precautions for storage**

Do not store above 25°C.

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

Clear glass bottle with a polyethylene cap and polyethylene sprinkle insert (50, 55, 110, 160 ml)

### **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  
Medlock Street  
Oldham  
Lancashire OL1 3HS  
England

## **8 MARKETING AUTHORISATION NUMBER**

PA 0618/010/001

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

Date of first authorisation: 01 June 1977

Date of last renewal: 01 June 2002

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

May 2003