

**IRISH MEDICINES BOARD ACTS 1995 AND 2006**

**MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007**

**(S.I. No.540 of 2007)**

**PA0299/010/001**

Case No: 2036411

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

**E.C. De Witt & Company Limited**

**Aegon House, Daresbury Park, Daresbury, Warrington, Cheshire WA4 4HS, United Kingdom**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

**Clinicide Lotion 0.5 %w/w Cutaneous Solution**

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **20/10/2007**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Clinicide Lotion, 0.5% w/w Cutaneous Solution

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Carbaryl 0.5% w/w.

For a full list of excipients, see section 6.1.

#### 3 PHARMACEUTICAL FORM

Cutaneous solution

A clear, pale yellow, straw coloured mobile liquid.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

For the treatment of hair infestations specifically head lice and pubic lice. For treatment only and not for the prevention of head lice.

For topical administration only.

When a member of your family need treatment, other family members should be checked for live lice and treated only if infestation is found.

##### 4.2 Posology and method of administration

###### Adults and children

Shake well before use.

###### **For Head Lice**

- a. Apply freely to roots of dry hair and scalp, paying special attention to partings, back of neck and behind ears.
- b. Allow hair to dry naturally.
- c. Wash hair with ordinary shampoo next day.
- d. While the hair is still wet use a metal comb to remove dead lice and eggs (nits).

###### **For Pubic Lice**

- a. Apply freely to all parts of the hair in affected areas paying special attention to roots.
- b. Allow to dry naturally and use a bland shampoo next day.

##### 4.3 Contraindications

Hypersensitivity to the active substance or to any .of the excipients.

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

Shake the bottle before use.  
For external use only.

Allow hair to dry naturally. Do not use a hair dryer. Take care to avoid eyes.

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

Health workers in mass treatment campaigns are advised to wear plastic or rubber gloves.

Keep all medicines out of the reach and sight of children.

Local health authorities have a policy of using insecticides in sequence to discourage resistance. It is advisable to check on local current policy.

Continued prolonged treatment with carbaryl containing products should be avoided. They should not be used more than once a week and for no longer than three consecutive weeks.

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

Not applicable.

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

Not applicable.

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

Not applicable.

#### **4.8 Undesirable effects**

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**

It is unlikely that a toxic dose of Carbaryl will be ingested. Treatment consists of gastric lavage, assisted respiration and if necessary administration of atropine.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

P03AX - Other ectoparasiticides, incl. scabicides.

Carbaryl is a carbamate pesticide, which is also used for the treatment of pediculosis capitis.

#### **5.2 Pharmacokinetic properties**

Not applicable.

### **5.3 Preclinical safety data**

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.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Macrogol 7 glycerol cocoate

Denatured ethanol

Citric acid monohydrate

Sodium citrate

Deionised water

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf Life**

30 months.

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

Do not store above 25°C.

Keep container in the outer carton.

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

50 ml HDPE bottle with screw cap.

### **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**

E C De Witt & Company Ltd

Tudor Road

Manor Park

Runcorn WA7 1SZ

United Kingdom

## **8 MARKETING AUTHORISATION NUMBER**

PA 299/10/1

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

Date of first authorisation: 20 October 1987

Date of last renewal: 20 October 2007

**10 DATE OF REVISION OF THE TEXT**

October 2007