

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Dentinox Cradle Cap Treatment Shampoo

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium lauryl ether sulpho-succinate 6.00% w/w.

Sodium lauryl ether sulphate 2.70% w/w.

For excipients, see section 6.1.

#### 3 PHARMACEUTICAL FORM

Shampoo

A clear, colourless shampoo.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

For the treatment of infant cradle cap, and general care of infant scalp, and hair.

##### 4.2 Posology and method of administration

Two shampoo applications of between 2-3ml. Repeat at each bath-time until the scalp is clear. Then use as necessary. Wet the baby's head with warm water. Squeeze a little Dentinox Cradle Cap Treatment Shampoo onto your palm, and massage gently but firmly over the entire scalp. Do not be afraid of touching the soft area of the scalp (fontanelle). Rinse off and repeat application. Rinse well and dry.

##### 4.3 Contraindications

Avoid contact with the eyes. Hypersensitivity to any of the ingredients.

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

For external applications only.

Keep all medicines out of the reach of children.

##### 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**

There have been very rare reports of erythema and skin irritation following the use of Dentinox Cradle Cap Treatment Shampoo.

#### **4.9 Overdose**

Overdosage by external application will not be a problem. Shampoo is non-toxic if ingested.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Dentinox Cradle Cap Treatment Shampoo contains two principal cleansing surfactants:

a) Sodium lauryl ether sulphate – an anionic surfactant widely used in cosmetics and toiletries,

and

b) Sodium lauryl ether sulpho-succinate – a secondary anionic surfactant employed on account of its exceptionally mild character.

A clinical trial carried out by Huntingdon Research Centre found that the product was effective in 25 out of 26 patients treated. A 1% cetavlon placebo was used as a control.

The product is non-toxic, and has similar eye irritation potential to typical family shampoos though less than anti-dandruff shampoos.

#### **5.2 Pharmacokinetic properties**

Not applicable.

Dentinox Cradle Cap Treatment Shampoo has a cleansing action. The product is massaged into the scalp with a little water, then rinsed off.

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

Not applicable.

### **6 PHARMACEUTICAL PARTICULARS**

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

Sodium salt of coconut imidazoline

Oleic acid diethanolamide

Sodium chloride

Rose perfume

Purified water

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf Life**

3 years.

## **6.4 Special precautions for storage**

Do not store above 25 °C.

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

125 ml white high density polythene bottle with snap fit closure in white polypropylene.  
Each container packed in a unit carton. Pack size 125 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**

DDD Limited  
94 Rickmansworth Road  
Watford  
Hertfordshire WD18 7JJ  
United Kingdom

## **8 MARKETING AUTHORISATION NUMBER**

PA 302/11/1

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

Date of first authorisation: 09 January 1995

Date of last renewal: 09 January 2005

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

September 2006