

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dentinox Cradle Cap Treatment Shampoo, Sodium lauryl ether sulpho-succinate 6% w/w, Sodium lauryl ether sulphate 2.7% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium lauryl ether sulpho-succinate 6.00% w/w.
Sodium lauryl ether sulphate 2.70% w/w.

Excipients with known effect:
Sodium benzoate (E 211) 0.6 mg/ml
For a full list of 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.
Dentinox Cradle Cap Treatment Shampoo is suitable for use from birth onwards.

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). Avoid excess massaging and use of hot water. Rinse off and repeat application. Rinse well and gently dry.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

Do not use on broken or infected skin.

4.4 Special warnings and precautions for use

For external applications only.

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

This medicine contains 1.8 mg Sodium benzoate (E 211) in each application (3 ml) which is equivalent to 0.6 mg/ml. Sodium benzoate (E 211) may cause local irritation. It may cause non-immunologic immediate contact reactions by a possible cholinergic mechanism.

Avoid contact with eyes.

Skin irritation may occur. To test for hypersensitivity, the shampoo should be applied to a small area and washed off after a few minutes. If the treated area shows signs of redness or inflammation within twenty-four hours, the product should not be used on the scalp. Treatment should be discontinued if there are any signs of skin reaction.

Avoid excess massaging, use of very hot water or use of other shampoos at the same time as Dentinox Cradle Cap Treatment Shampoo as these may irritate the skin. Do not try to remove the scales by picking at them as this could lead to secondary infection.

Atopic dermatitis may be exacerbated by use of surfactants such as Dentinox Cradle Cap Treatment Shampoo. Do not use if there are signs of atopic eczema such as itching, erythema, swelling/blistering or skin cracking, dryness or exfoliation.

Paediatric population:

Sodium benzoate may (E 211) increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old). Absorption of sodium benzoate through the immature skin of neonates is significant.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable.

4.6 Fertility, pregnancy and lactation

Not applicable.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Tabulated list of adverse reactions:

System Organ Class	Frequency	Adverse Event
General disorders and administration site conditions	Not known	Application site hypersensitivity Application site erythema Application site irritation Application site inflammation Application site alopecia Application site dryness

Hair loss may occur as hairs caught in the cradle cap will be removed when the patch falls off. This is part of the natural history of the condition.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Website: www.hpra.ie.

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

Polyoxyethylene rapeseedamide

Sodium chloride

Dilute hydrochloric acid

Rose perfume

Purified water

Sodium Benzoate (E 211)

See leaflet for further information

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

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Ireland

8 MARKETING AUTHORISATION NUMBER

PA1113/020/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 09 January 1995

Date of last renewal: 09 January 2010

10 DATE OF REVISION OF THE TEXT

April 2025