

**PACKAGE LEAFLET**

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Dentinox Cradle Cap Treatment Shampoo**

Sodium lauryl ether sulpho-succinate 6% w/w

Sodium lauryl ether sulphate 2.7% w/w

**Read all of this leaflet carefully before you start using this medicine.**

Keep this leaflet, you may need to read it again. If you need more information or advice speak to your health visitor, pharmacist or doctor.

#### **In this leaflet:**

1. What Dentinox Cradle Cap Treatment Shampoo is and what it is used for
2. Before you use Dentinox Cradle Cap Treatment Shampoo
3. How you use Dentinox Cradle Cap Treatment Shampoo
4. Possible side effects
5. How to store Dentinox Cradle Cap Treatment Shampoo
6. Further information
7. About cradle cap

#### **1. What Dentinox Cradle Cap Treatment Shampoo is and what it is used for**

Dentinox Cradle Cap Treatment Shampoo is a clear colourless shampoo containing the active ingredients sodium lauryl ether sulpho-succinate and sodium lauryl ether sulphate, which belong to a group of medicines called cleansing surfactants. These cleansers have been shown to be effective in the treatment of cradle cap.

Dentinox Cradle Cap Treatment Shampoo is for the treatment of infant cradle cap, and general care of infant scalp and hair.

This shampoo is suitable to use from birth onwards.

#### **2. Before you use Dentinox Cradle Cap Treatment Shampoo**

**You should not use Dentinox Cradle Cap Treatment Shampoo:**

- **If your baby is allergic** (hypersensitive) to **sodium lauryl ether sulpho-succinate, sodium lauryl ether sulphate, or any other ingredients of Dentinox Cradle Cap Treatment Shampoo** (see list of ingredients in Section 6).
- **If the skin on the scalp is broken.**
- **If there are signs of scalp infection** (redness, blistering, oozing, warmth)

#### **Important Information about some of the ingredients of Cradle Cap Treatment Shampoo**

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 increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

Sodium benzoate (E 211) may cause local irritation.

#### **Take special care with Dentinox Cradle Cap Treatment Shampoo.**

- Avoid contact with the eyes.
- Do not use if your baby has any signs of eczema on the scalp such as redness, swelling, blistering, dryness or cracking of the skin.
- Test on a small area of the infant's skin the day before you intend to use the shampoo. Do not use if any signs of redness or skin irritation occur within 24 hours of the test.
- Do not use other shampoos at the same time as this can make the skin very dry.
- If condition persists consult your doctor.

### 3. How you use Dentinox Cradle Cap Treatment Shampoo

**Dosage:** Use two shampoo applications of between 2-3 ml. 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 hot water. Rinse off and repeat application. Rinse well and gently dry. Do not try to remove the cradle cap by picking at it.

#### **If you use more Dentinox Cradle Cap Treatment Shampoo than you should:**

- Too much Dentinox Cradle Cap Treatment Shampoo on the skin will not be a problem. The shampoo is **not** poisonous if it is accidentally swallowed.

#### **If the product gets into the eyes**

The product, or lather, may cause irritation if it gets into the eyes. If this happens, rinse with plenty of clean water. If rinsing one eye, take care to avoid washing product into the other eye. If irritation persists, contact a doctor or pharmacist.

If you have any further questions on the use of this product, speak to your health visitor, pharmacist or doctor.

### 4. Possible side effects

Like all medicines, Dentinox Cradle Cap Treatment Shampoo can cause side effects, although these do not affect everybody.

#### **STOP using Dentinox Cradle Cap Treatment Shampoo and seek medical advice if:**

Not known (frequency cannot be estimated from available data)

- You notice signs of skin sensitivity (allergy)

#### **Other possible side effects**

**Frequency not known** (frequency cannot be estimated from available data)

- scalp redness,
- skin irritation
- skin inflammation
- skin dryness.

Hair loss can occur naturally when hair stuck in the cradle cap falls off with the patch. This is normal and the hair will grow back naturally.

#### **Reporting of side effects**

If your baby experiences any side effects, consult your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

### 5. How to store Dentinox Cradle Cap Treatment Shampoo

Dentinox Cradle Cap Treatment Shampoo should be kept out of the reach and sight of children. Do not store above 25 °C.

Do not use Dentinox Cradle Cap Treatment Shampoo after the expiry date which is stated on the carton and the bottle after EXP. The expiry date refers to the last day of the month.

## **6. Further information**

### **What Dentinox Cradle Cap Treatment Shampoo contains:**

The active substances are sodium lauryl ether sulpho-succinate 6% w/w and sodium lauryl ether sulphate 2.7% w/w. The other ingredients are: sodium salt of coconut imidazoline, polyoxyethylene rapeseedamide, , sodium chloride, dilute hydrochloric acid, rose perfume, sodium benzoate (E 211) and purified water.

### **What Dentinox Cradle Cap Treatment Shampoo looks like and contents of the pack:**

Dentinox Cradle Cap Treatment Shampoo is available in white plastic bottles containing 125 ml.

### **Marketing Authorisation Holder:**

Phoenix Labs, Suite 12, Bunkilla Plaza, Bracetown Business Park, Clonee, Co. Meath, Ireland.

### **Manufacturer:**

LABORATORI FUNDACIÓ DAU, C/C, 12-14, Pol. Ind. Consorci Zona Franca, 08040 Barcelona, Spain.

## **7. About cradle cap**

Cradle cap is a condition of the skin called seborrhoeic dermatitis, which causes a dry, flaky, itchy scalp. It is not serious, but it makes the skin on baby's head look scaly. You can use the shampoo to clear baby's head of flakiness, and as a general shampoo once cradle cap has cleared up, to keep baby's scalp and hair clean and healthy.

This leaflet was last revised in April 2025