

## Package leaflet: Information for the user

### Capasal Therapeutic Shampoo

salicylic acid, coconut oil, distilled coal tar

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

**Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.**

**Keep this leaflet. You may need to read it again. Ask your doctor, pharmacist or nurse if you need more information or advice. If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4. You must talk to a doctor if your skin condition is not improving or if it feels worse after 4 weeks.**

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

1. What Capasal Therapeutic Shampoo is and what it is used for
2. What you need to know before you use Capasal Therapeutic Shampoo
3. How to use Capasal Therapeutic Shampoo
4. Possible side effects
5. How to store Capasal Therapeutic Shampoo
6. Contents of the pack and other information

### **1. WHAT CAPASAL THERAPEUTIC SHAMPOO IS AND WHAT IT IS USED FOR**

- Capasal Therapeutic Shampoo is a treatment for dry, scaly scalp conditions such as:
  - seborrhoeic eczema / seborrheic dermatitis (patches of red, scaly, itchy skin);
  - pityriasis capitis (severe dandruff);
  - cradle cap (thick, yellowish, scaly scalp rash in babies and infants), and;
  - psoriasis (areas of raised, red, sometimes itchy, patches of skin, covered with silvery scales, **without** any blistering or tenderness).
- Capasal Therapeutic Shampoo can also be used to remove other medicines applied to the scalp.
- Capasal Therapeutic Shampoo is for use by **adults, the elderly, children, infants and babies.**
- This product contains three active ingredients:
  - **salicylic acid** to remove scaly, flaky skin;
  - **coconut oil** to soften, moisturise and lubricate the scalp, and;
  - **distilled coal tar** to stop itching and restore normal skin development.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU USE CAPASAL THERAPEUTIC SHAMPOO**

**Do not use Capasal Therapeutic Shampoo** if you are **allergic (hypersensitive)** to salicylic acid, coconut oil, distilled coal tar or any of the other ingredients of Capasal Therapeutic Shampoo listed in Section 6.

#### **Warnings and precautions**

**Take special care** when using this product:

Keep the undiluted shampoo, and the lather, away from the eyes.

Capasal Therapeutic Shampoo contains 0.15 mg of sodium benzoate in each gram of shampoo. Sodium benzoate (E 211) may cause local irritation. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

#### **Other medicines and Capasal Therapeutic Shampoo**

This product is not known to affect, or to be affected by, any other medicines.

#### **Pregnancy and breast-feeding**

The ingredients have been in widespread use in this and similar preparations for many years, without reports of problems. However, safety trials have not been conducted. This product is therefore not recommended during the first three months of pregnancy. After the first three months of pregnancy it should only be used intermittently.

#### **Driving and using machinery**

Using this product is not known to affect your ability to drive or use machinery.

### **3. HOW TO USE CAPASAL THERAPEUTIC SHAMPOO**

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Use Capasal Therapeutic Shampoo only to treat the scalp conditions that it is intended for.

Use as a shampoo until the scalp looks and feels better or as recommended by your doctor, pharmacist or nurse. Capasal can be used once or twice a week until your condition improves. Thereafter, occasional use may be necessary.

#### **For adults, the elderly, children, infants and babies:**

- Wet the hair thoroughly.
- Apply a small amount of shampoo to the scalp (approximately a quantity the size of a two Euro piece for short hair, adjusting up depending on length/thickness of hair).
- With the tips of the fingers, massage in thoroughly.
- Leave on for a few minutes.
- Remove as much lather as possible with the hands (this is important as it will take the scales with it).
- Rinse out.
- If necessary, repeat the steps above.
- Rinse out well under running water, then dry the hair as normal.

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

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

#### **If you forget to use Capasal Therapeutic Shampoo**

Do not worry if you occasionally forget to use this product, just carry on using it when you remember.

If there is no improvement after 4 weeks, or if your scalp condition seems to look or feel worse, discontinue use of the product and consult your doctor, pharmacist or nurse.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Capasal Therapeutic Shampoo can cause side effects, although not everybody gets them.

- This product has been specially designed for use on dry or problem skin, but in some rare cases it can cause irritant or allergic skin reactions on extremely sensitive skin. These rare effects tend to occur during or soon after the first few uses.
- Because of a theoretical risk of skin damage if used for long periods, if your scalp condition does not get better after a while, tell your doctor or pharmacist before continuing treatment.

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

If you get any side effects, talk to 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 CAPASAL THERAPEUTIC SHAMPOO**

- Keep this medicine out of the sight and reach of children.
- Always replace the cap tightly after use.
- Keep the bottle in the outer carton.
- Keep away from direct sunlight.
- Do not store the product above 25°C.
- Do not use this medicine after the expiry date which is stated on the bottle and carton after EXP. The expiry date refers to the last day of that month.
- Do not throw away any unused medicines via wastewater or household waste. Ask your pharmacist how to throw away any unused medicines you no longer use. These measures will help to protect the environment.

#### **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

##### **What Capasal Therapeutic Shampoo contains:**

The **active ingredients** are **salicylic acid** (0.5% w/w), **coconut oil** (1.0% w/w) and **distilled coal tar** (1.0% w/w).

The **other ingredients** are lauric acid diethanolamide, coco amido propyl dimethyl betaine solution (contains sodium benzoate as a preservative), triethanolamine lauryl sulfate solution (contains methylchloroisothiazolinone/methylisothiazolinone (3:1) as a preservative), ammonium sulfate, phenoxyethanol and purified water.

##### **What Capasal Therapeutic Shampoo looks like and contents of the pack**

The product is a golden brown shampoo that smells of coal tar. The product is available in 100 and 250 ml plastic bottles fitted with dispensing caps. (30 ml bottles are also available to medical and allied professionals.)

**The Marketing Authorisation holder is** Dermal Laboratories (Ireland) Limited, 38 Main Street, Swords, County Dublin, K67E0A2, Ireland.

**The Manufacturer is** Fleet Laboratories Ltd, 94 Rickmansworth Rd, Watford, Herts, WD18 7JJ, UK OR Aeropak, Viking Road, Great Yarmouth, NR31 0NU, UK.

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