



CapasalTM Therapeutic Shampoo

salicylic acid, coconut oil, distilled coal tar

Read all of this leaflet carefully before using this product.

Keep this leaflet. You may need to read it again.

Ask your doctor or pharmacist if you need more information or advice.

If any of the side effects get serious or if you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.

In this leaflet:

1. What Capasal Therapeutic Shampoo is and what it is used for
2. Before you use Capasal Therapeutic Shampoo
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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 / seborrhoeic 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. 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.

Take special care when using this product: Keep the undiluted shampoo, and the lather, away from the eyes.

Using other medicines

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

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

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

Use as a shampoo, once or twice weekly, or as often as recommended by your doctor or pharmacist:

- Wet the hair thoroughly.
- Apply a small amount of shampoo to the scalp.
- 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.
- Repeat the steps above.
- Rinse out well under running water, then dry the hair as normal.

Carry on using it in this way for as long as recommended by your doctor or pharmacist.

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 this product

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

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

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.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, stop using the product and tell your doctor or pharmacist.

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 HPRAs Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@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 it out of the reach and sight 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 after the expiry date shown on the bottle and carton. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION ABOUT CAPASAL THERAPEUTIC SHAMPOO**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, triethanolamine lauryl sulfate solution, ammonium sulfate, phenoxyethanol and 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, Tatmore Place, Gosmore, Hitchin, Herts, SG4 7QR, UK.

The Manufacturer is Fleet Laboratories Ltd, 94 Rickmansworth Rd, Watford, Herts, WD18 7JJ, UK.

This leaflet was last revised in January 2015.