Psoriderm[™] scalp lotion shampoo

distilled coal tar 2.5% w/v, lecithin 0.3% w/v

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:

- What Psoriderm Scalp Lotion Shampoo is and what it is used for
- 2. Before you use Psoriderm Scalp Lotion Shampoo
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WHAT PSORIDERM SCALP LOTION SHAMPOO IS AND WHAT IT IS USED FOR

- Psoriderm Scalp Lotion Shampoo is a shampoo treatment for scalp psoriasis (areas of raised, red, sometimes itchy, patches of skin, covered with silvery scales without any blistering or tenderness).
- The shampoo is for use by adults, the elderly and children.
- This product contains two active ingredients:
 - lecithin, which softens the skin, helping to increase the action of the distilled coal tar;
 - **distilled coal tar**, which stops itching and restores normal skin development.

2. BEFORE YOU USE PSORIDERM SCALP LOTION SHAMPOO

Do not use the product:

- if you are allergic (hypersensitive)
 to distilled coal tar, lecithin or any of the other
 ingredients of Psoriderm Scalp Lotion
 Shampoo listed in Section 6;
- on psoriasis that feels and looks sore and angry, or on pustular psoriasis (which is very tender, inflamed, and involves small blisters filled with pus);
- on infected skin.

Take special care when using this product: Keep the undiluted shampoo, and the lather, away from the eyes, mouth and the inside of your nose.

Using other medicines

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

Pregnancy and breast-feeding

This product can be used during pregnancy and whilst 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.

Driving and using machinery

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

3. HOW TO USE PSORIDERM SCALP LOTION SHAMPOO

Use this product only as a shampoo to treat scalp psoriasis.

For adults, the elderly and children:

Use as a shampoo, daily if necessary, until your scalp condition gets better:

- 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.

If the shampoo gets into the eyes, nose or mouth

This product, or the lather, may cause irritation if it gets into the eyes, nose or mouth. If this happens, rinse the affected areas with plenty of water. If rinsing one eye, take care to avoid washing product into the other eye. If irritation persists, tell your doctor or pharmacist.

If you use too much of this product

Do not worry if you use too much shampoo, simply rinse hair under running water and continue as instructed above.

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, this product can cause side effects, although not everybody gets them.

- The following can occur rarely, in which case you should stop using the product:
 - skin irritation:
 - acne-like eruptions;
 - skin photo-sensitivity (sensitivity to sunlight).
- In rare cases, it may stain the skin, hair or fabric.

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.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme at: www.mhra.gov.uk/ yellowcard

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971;

Fax: +353 1 6762517. Website: www.hpra.ie;

E-mail: medsafetv@hpra.ie.

5. HOW TO STORE PSORIDERM SCALP LOTION SHAMPOO

- · Keep it out of the reach and sight of children.
- Always replace the cap tightly after use.
- Do not store the product above 25°C.
- Do not use after the expiry date shown on the bottle and the carton. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via household refuse. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION ABOUT PSORIDERM SCALP LOTION SHAMPOO

What Psoriderm Scalp Lotion Shampoo contains: The active ingredients are **distilled coal tar** (2.5% w/v) and **lecithin** (0.3% w/v).

The **other ingredients** are trolamine laurilsulfate, lauric acid diethanolamide, ammonium sulfate, disodium edetate, sodium chloride, phenoxyethanol and purified water.

What Psoriderm Scalp Lotion Shampoo looks like and contents of the pack

- · The product is a golden brown shampoo.
- The shampoo is available in white plastic bottles containing 250ml fitted with screw caps.

The Marketing Authorisation holder is

Dermal Laboratories, Tatmore Place, Gosmore, Hitchin, Herts. SG4 7QR, UK.

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

To listen to or request a copy of this leaflet in Braille, large print or audio, please call free of charge: 0800 198 5000 (UK only). Please be ready to give the following information: Psoriderm Scalp Lotion Shampoo, 00173/5001. This is a service provided by the Royal National Institute of Blind People (RNIB).