

Psoriderm™ emulsion 40% w/v bath additive

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 Psoriderm Emulsion Bath Additive is and what it is used for
2. Before you use Psoriderm Emulsion Bath Additive
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1. WHAT PSORIDERM EMULSION BATH ADDITIVE IS AND WHAT IT IS USED FOR

- Psoriderm Emulsion Bath Additive is a treatment for you to add to your bath water when bathing.
- It helps treat a particular type of psoriasis that doctors refer to as sub-acute or chronic plaque psoriasis.
- This type of psoriasis involves areas of raised, red, sometimes itchy, patches of skin, covered with silvery scales (**without** any blistering or tenderness). The patches often occur on the elbows, knees, lower back and scalp.
- This product is recommended for use by **adults, the elderly and children**.
- The active ingredient in this product is **distilled coal tar**, which stops itching and restores normal skin development.

2. BEFORE YOU USE PSORIDERM EMULSION BATH ADDITIVE

Do not use Psoriderm Emulsion Bath Additive:

- if you are **allergic (hypersensitive)** to distilled coal tar or any of the other ingredients of Psoriderm Emulsion Bath Additive 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:

- Do not use it undiluted.
- Avoid spilling it.
- Keep it away from the eyes, and broken or inflamed skin.

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 EMULSION BATH ADDITIVE

Use this product only to treat the particular type of psoriasis that it is recommended for.

For adults, the elderly and children:

- Add 30ml of the product to a bath of warm water
- Soak for 5 minutes.
- **Pat** the skin dry with a **soft** towel.
- **Avoid rubbing** with the towel because this makes skin conditions worse.

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If the product gets into the eyes, nose or mouth

The product 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 Psoriderm Emulsion Bath Additive. Simply adjust the amount of water in the bath.

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, Psoriderm Emulsion Bath Additive 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: medsafety@hpra.ie.

5. HOW TO STORE PSORIDERM EMULSION BATH ADDITIVE

- 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 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 EMULSION BATH ADDITIVE

What Psoriderm Emulsion Bath Additive contains:

The active ingredient is **distilled coal tar** (40.0% w/v).

The **other ingredients** are polysorbate 20, trolamine, phenoxyethanol and purified water.

What Psoriderm Emulsion Bath Additive looks like and contents of the pack

- The product is a buff-coloured liquid emulsion.
- It is available in amber glass bottles containing 200ml. The bottles are 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 Emulsion Bath Additive, 00173/5003. This is a service provided by the Royal National Institute of Blind People (RNIB).