

Package leaflet: Information for the user

exorex[®] lotion

5% v/w Cutaneous Emulsion Coal Tar Solution

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 or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

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

1. What Exorex Lotion is and what it is used for

Exorex Lotion is a skin lotion (also known as cutaneous emulsion) for external use only. It contains coal tar solution which relieves and prevents itching and promotes the softening of the outer layer of skin. The tar acids in coal tar have been shown to have anti-bacterial properties. Exorex Lotion is for the treatment of psoriasis.

2. What you need to know before you use Exorex Lotion

Do not use Exorex Lotion:

- If you are allergic to coal tar or any of the other ingredients of this medicine (listed in section 6).
- If you suffer from inflammation of the hair follicles (folliculitis) or acne.
- If your skin reacts badly to sunlight (you are photosensitive).
- If you suffer from a condition called lupus erythematosus.
- If you have inflamed or broken skin (you have open wounds or your skin is infected).
- On the genital or rectal areas.

Warnings and precautions

Talk to your doctor or pharmacist before using Exorex Lotion.

- Be careful when applying the lotion around the eyes and other sensitive areas of the body such as the mouth. If any lotion accidentally enters the eyes, rinse with water immediately.
- Coal tar makes the skin more sensitive to sunlight. Exposure to direct sunlight (such as sunbathing) should therefore be avoided after application of the lotion. There may be a very small increase in the risk of skin cancer in patients with psoriasis who are treated with coal tar products, but this is not proven.
- Exorex Lotion may cause staining of clothes or hair.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Other medicines and Exorex Lotion

You can use Exorex Lotion whilst taking other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Exorex Lotion contains propyl hydroxybenzoate (E216), methylhydroxybenzoate (E218) and hydrogenated polyoxyl castor oil.

Propyl hydroxybenzoate (E216) and methylhydroxybenzoate (E218) may cause allergic reactions (possibly delayed). Hydrogenated polyoxyl castor oil may cause skin reactions.

3. How to use Exorex Lotion

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

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Dosage and method of administration

Exorex Lotion is for the treatment of psoriasis of the skin and scalp.
Shake the bottle thoroughly before each use.

Adults and children over 12 years of age

- Ensure that all areas of affected skin are clean.
- Apply a thin layer of Exorex Lotion two to three times a day to affected areas.
- Massage gently and leave to dry.

Children under 12 years and the elderly

- As for adults, but the lotion can be diluted by mixing with a few drops of freshly boiled and cooled water in the palm of the hand if preferred.

Previous users have found the application of a thin layer of moisturising cream to be helpful in keeping the affected areas moist after application of the lotion.

If you use more Exorex Lotion than you should

This is unlikely to be harmful but may result in allergy (hypersensitivity) to coal tar.

If you accidentally swallow Exorex Lotion

If any Exorex Lotion is accidentally swallowed call your doctor immediately or go to the nearest hospital Accident and Emergency department. Take the bottle with you so that the product may be easily identified.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You may experience skin irritation, increased sensitivity of the skin to sunlight, or acne-like outbreaks of the skin. If this happens consult 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)

United Kingdom

The 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

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Exorex Lotion

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle after 'EXP' or 'Expiry Date'. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use.

These measures will help protect the environment.

6. Contents of the pack and other information

What Exorex Lotion contains

The active substance is: Coal Tar Solution 5% v/w.

The other ingredients are: polysorbate 80, ethanol, dl-alpha tocopherol, xanthan gum, vitamin F ethyl ester, hydrogenated polyoxyl castor oil, propyl hydroxybenzoate (E216), methyl hydroxybenzoate (E218), purified water.

What Exorex Lotion looks like and contents of the pack

Exorex Lotion is a smooth mustard-coloured cutaneous emulsion (skin lotion).

It is available in bottles of 100 ml and 250 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder- United Kingdom

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PL 00289/2306

Marketing Authorisation Holder- Ireland

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PA1986/078/001

Manufacturer

Purna Pharmaceuticals N.V., Rijksweg 17, 2870 Puurs, Belgium.

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