

PACKAGE LEAFLET

Information for the user

Emulsiderm Emollient

Bath additive/Cutaneous emulsion

liquid paraffin 25% w/w, isopropyl myristate 25% w/w, benzalkonium chloride 0.5% w/w

Please read all of this leaflet carefully before you start using this medicine.

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

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

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In this leaflet:

1. What Emulsiderm Emollient is and what it is used for
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1. WHAT EMULSIDERM EMOLLIENT IS AND WHAT IT IS USED FOR

- Emulsiderm Emollient is an antimicrobial and emollient (softening and moisturising) treatment for dry and problem skin.
- It is for use in two ways:
 - for adding to your bath water
 - as a leave-on application, by application directly to the skin
- It helps to treat and prevent dry and itchy (pruritic) skin conditions, especially eczema and dermatitis.
- **All age groups** can use Emulsiderm Emollient, including babies.
- There are two types of **active ingredient** in this product:
 - Benzalkonium chloride is an **antimicrobial**. This helps to:
 - combat bacteria present on your skin that can make eczema worse
 - prevent infection caused by scratching itchy skin.
 - Liquid paraffin and isopropyl myristate are **emollients** which help to;
 - soften, moisturise and protect your skin by trapping moisture in the skin and restoring the normal protective function of the skin
 - prevent the skin-drying and irritant effects that can be caused by washing and bathing and by the soaps, foaming additives and fragrances used in ordinary skin cleansing products.
- This product can be used in addition to any other emollients or treatments your doctor or pharmacist may have given or prescribed for you to treat your dry skin condition.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE EMULSIDERM EMOLLIENT

Do not use this product if you are allergic (hypersensitive) to benzalkonium chloride, liquid paraffin, isopropyl myristate, or any of the other ingredients of Emulsiderm Emollient listed in Section 6.

Warnings and precautions

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.

Take special care when using this product:

- If using as a leave-on application, it is generally a good idea for patients with very sensitive skin to start any new treatment on a small test area first, in case any side effect occurs (see Section 4 below). This is especially important when treating the face or young children. Thereafter, treatments may be applied more generously, as required.
- Avoid getting it in the eyes, especially when using it on the face.
- It can make your bath slippery, so be careful to avoid slipping over when getting into and out of your bath. Be careful when handling babies and young children.
- After use, clean out the bath with a suitable detergent to remove any remaining greasiness (wearing protective gloves to avoid irritating your hands).

Using other medicines

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

Pregnancy and breast-feeding

This product can be used during pregnancy and whilst breast-feeding. However, when breast-feeding, if use on the breast and nipple area is necessary, this product should be applied sparingly and after feeds. Gently wipe away any remaining product before feeding your baby. This is to avoid your baby taking in the product from the surface of your skin during 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.

3. HOW TO USE EMULSIDERM EMOLLIENT

For maximum benefit, add this product to your bath water every time you have a bath.

The same instructions apply for all age groups: -

For use in the bath:

- **Shake the bottle before use.**
- Add up to 30 ml to a normal-sized bath filled with warm water (for the 300 ml bottle use up to 2 capfuls. For the 1000 ml (1L) bottle use the measuring cup supplied).
- Get into the bath and cover the affected areas of skin with the bath water.
- Soak for 5 to 10 minutes.
- **Pat** the skin dry with a **soft** towel.
- **Avoid rubbing** with the towel because this makes dry skin conditions worse.

It is not necessary to use soap for additional cleansing. If desired, however, a fragrance-free soap substitute should be used. This type of product does not foam or lather.

For application to the skin:

- Smooth a small amount of undiluted product into the dry areas of skin until absorbed.

If you forget to use Emulsiderm Emollient

Do not worry if you occasionally forget to use it, just carry on using the product as described the next time you require it.

If the product gets into the eyes

The product may cause irritation if it gets into the eyes. Rinse the eyes with plenty of water.

If rinsing one eye, take care to avoid washing product into the other eye. If irritation persists, seek medical advice.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Emulsiderm Emollient can cause side effects, although not everybody gets them.

This product has been specially designed for use on dry or problem skin areas anywhere on the body, but in some very rare cases it can cause local skin reactions (involving redness, irritation and/or itching). These very rare skin reactions may become more significant where associated with excessive use as a leave-on application in areas of folded skin such as the groin or in the nappy area.

Stop using this emollient and **tell** your doctor or pharmacist:

- If your skin condition seems to look or feel worse.
- If any of the side effects become unacceptable, or you notice any other side effects not mentioned in this leaflet.

If you swallow Emulsiderm Emollient

If you accidentally **swallow** the product and you then feel unwell, seek medical attention.

Do not attempt to cause vomiting.

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 the HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE EMULSIDERM EMOLLIENT

- Keep out of sight and reach of children.
- Do not use Emulsiderm Emollient after the expiry date shown on the container and carton. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Always replace the cap after use

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Emulsiderm Emollient contains:

The **active ingredients** in this product are **benzalkonium chloride** (0.5% w/w), **liquid paraffin** (25% w/w) and **isopropyl myristate** (25% w/w).

The **other ingredients** are sorbitan stearate, polysorbate 60, industrial methylated spirit and purified water.

What Emulsiderm Emollient looks like and contents of the pack

- The product is a white cutaneous (skin) emulsion and bath additive that contains no fragrance.
- It is available in a plastic bottle containing 300 ml fitted with a cap, or a plastic bottle containing 1000 ml (1L) fitted with a cap and measuring cup.

Marketing Authorisation holder

Dermal Laboratories (Ireland) Ltd, Co Dublin, K67 E0A2.

Manufacturer

Jenson R+ (Ireland) Limited, Unit 15, Daingean Hall, N4 Axis Centre, Longford, N39 W6K0, Ireland

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7. GENERAL ADVICE ON LOOKING AFTER DRY SKIN CONDITIONS

- Emollients help soften, moisturise and protect the skin. They play a central role in the treatment and management of dry skin conditions. For maximum effect, they should be applied regularly and as often as needed.
- When bathing, try to use warm, not hot, water and avoid staying in the bath for long periods. This could make dry skin conditions worse.
- Try to avoid using normal soaps or bath additives (even those labelled “moisturising”). This is because they tend to dry and irritate the skin. Avoid using products containing fragrances, as these can also cause skin problems. You should try to use a fragrance-free emollient “soap substitute” instead. This type of product will not foam or lather but will be better for your dry skin condition.

- **Breaking the itch-scratch cycle.**

Some dry skin conditions like eczema and dermatitis are itchy, and can be quite sore. Although scratching relieves the itching for a short while, it further damages the skin. Badly scratched skin easily gets infected. This makes it itchier and the urge to scratch becomes even greater. It is better if scratching can be avoided by reducing the itching. The regular use of emollients or moisturisers can help with this.