

PACKAGE LEAFLET

Information for the user



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.

In this leaflet:

- 1. What Dermol Cream is and what it is used for
- 2. Before you use Dermol Cream
- 3. How to use Dermol Cream
- 4. Possible side effects
- 5. How to store Dermol Cream
- 6. Further information
- 7. General advice on looking after dry skin conditions

1. WHAT DERMOL CREAM IS AND WHAT IT IS USED FOR

- Dermol Cream is an antimicrobial and emollient (softening and moisturising) treatment for application to dry or problem skin.
- It is for use in two ways:
 - as a leave-on application
 - as a soap-substitute.
- It helps treat and prevent dry and itchy (pruritic) skin conditions, especially eczema and dermatitis.
- All age groups can use Dermol Cream, including babies.
- There are two types of active ingredient in this product:
 - Benzalkonium chloride and chlorhexidine dihydrochloride are antimicrobials.
 These help 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. BEFORE YOU USE DERMOL CREAM

Do not use Dermol Cream if you are **allergic** (hypersensitive) to benzalkonium chloride, chlorhexidine dihydrochloride, liquid paraffin, isopropyl myristate, or any of the other ingredients of Dermol Cream listed in Section 6.

Take special care when using this product:

- For patients with very sensitive skin, it is generally a good idea 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.
- When used as a soap substitute in the bath or shower the product can make the surface slippery, so be careful to avoid slipping over when getting into and out of your shower or bath (eg by using a shower or bath mat).

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. 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.

Important information about one of the ingredients of Dermol Cream

The product contains cetostearyl alcohol. This ingredient may cause local skin reactions (eg contact dermatitis) in a small number of sensitive people. If you have been told by your doctor that you are sensitive to cetostearyl alcohol, please talk to your doctor before using this product.

3. HOW TO USE DERMOL CREAM

Use it only on the skin. For maximum benefit you should use it on a regular basis and as often as required.

Before using the 500 g bottle, turn the top of the pump dispenser anti-clockwise to unlock it. After unlocking, you will need to press down the pump dispenser several times to prime the pump before any product is dispensed.

The same instructions apply for all age groups:-

For use as a leave-on application:

- · Apply Dermol Cream to the affected areas.
- · Gently smooth into the skin.
- If necessary, allow time for any excess to soak in. Do not rub the skin vigorously.

- · Reapply as often as required.
- If you are applying another treatment to the same areas of skin as Dermol Cream, try to avoid mixing the two products. This can be achieved by applying the treatments alternately, leaving sufficient time to allow the previous application to soak in.

For use as a soap substitute

- Use Dermol Cream to wash with instead of your ordinary soap or shower gel.
 It will not foam or lather like ordinary cosmetic products.
- After washing, bathing or showering, pat the skin dry with a soft towel (avoid rubbing as this can make dry skin conditions worse).

If you forget to use Dermol Cream

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, Dermol Cream 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 cream 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 Dermol Cream

If you accidentally **swallow** the product and you then feel unwell, seek medical attention. **Do not attempt to cause vomiting.**

5. HOW TO STORE DERMOL CREAM

- · Keep out of reach and sight of children.
- Do not use Dermol Cream 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 30°C.
- Always replace the cap after use.
- In the case of the 500 g bottle, it is advisable to turn the top of the pump dispenser clockwise to lock it.

6. FURTHER INFORMATION

What Dermol Cream contains:

The active ingredients in this product are benzalkonium chloride (0.1% w/w), chlorhexidine dihydrochloride (0.1% w/w), liquid paraffin (10% w/w) and isopropyl myristate (10% w/w).

The **other ingredients** are cetostearyl alcohol, glycerol, macrogol cetostearyl ether (cetomacrogol 1000), phenoxyethanol, disodium phosphate dodecahydrate, sodium dihydrogen phosphate dihydrate and purified water.

What Dermol Cream looks like and contents of the pack

- The product is a white, non-greasy cream that contains no dye or fragrance.
- The product is available in a plastic bottle containing 500 g or in a plastic tube containing 100 g. (30 g packs are also available to the medical and allied professions).

The Marketing Authorisation holder is Dermal Laboratories, Hitchin, Herts, SG4 7QR, UK. **The Manufacturer is** Fleet Laboratories Ltd, 94 Rickmansworth Road, Watford, Herts, WD18 7JJ, UK.

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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 shower products (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.

 You may find it helpful to contact NHS Direct (tel: 0845 4647) or a patient support group such as the National Eczema Society (tel: 0800 0891122, 8am to 8pm Mon-Fri) for information about your skin condition.

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: Dermol Cream, 00173/0171.

This is a service provided by the Royal National Institute of Blind People (RNIB).