

# 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 500 Lotion is and what it is used for
2. Before you use Dermol 500 Lotion
3. How to use Dermol 500 Lotion
4. Possible side effects
5. How to store Dermol 500 Lotion
6. Further information
7. General advice on looking after dry skin conditions

## **1. WHAT DERMOL 500 LOTION IS AND WHAT IT IS USED FOR**

- Dermol 500 Lotion 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 500 Lotion, 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 500 LOTION**

**Do not use** Dermol 500 Lotion if you are **allergic** (hypersensitive) to benzalkonium chloride, chlorhexidine dihydrochloride, liquid paraffin, isopropyl myristate, or any of the other ingredients of Dermol 500 Lotion listed in Section 6.

### **Warnings and precautions**

As with any product, severe generalised allergic reactions (see Section 4) are possible. Very rare reports of such reactions in susceptible individuals, leading to a drop in blood pressure and even to unconsciousness, have been associated with products containing chlorhexidine. You must not use Dermol 500 Lotion if you have had problems with chlorhexidine-containing products in the past.

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 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 (e.g. 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. However, when breast-feeding, if use on the nipples is necessary, apply sparingly and after feeds. Gently wipe away any remaining product before feeding your baby. 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.

### **Dermol 500 Lotion contains cetostearyl alcohol**

Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

If you have previously experienced local skin reactions (e.g. contact dermatitis) to any of the ingredients, please talk to your doctor before using this product.

## **3. HOW TO USE DERMOL 500 LOTION**

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

Before using the 500 ml 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 500 Lotion 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 500 Lotion, 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 500 Lotion 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 500 Lotion

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 500 Lotion can cause side effects, although not everybody gets them.

If you experience any of the following reactions **stop using** Dermol 500 Lotion **and get urgent medical help**: swelling of the face, lips, tongue or throat; a sudden uncharacteristic red itchy skin rash (hives) away from the site of application; wheezing or breathing difficulty; feeling faint or dizzy; a strange metallic taste in the mouth; or collapse. You may be having a serious allergic reaction.

This product has been specially designed for use on dry or problem skin areas anywhere on the body. **Rarely**, Dermol 500 Lotion can cause skin reactions on treated areas (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 lotion 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 500 Lotion

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 Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can provide more information on the safety of this medicine.

## 5. HOW TO STORE DERMOL 500 LOTION

- Keep out of sight and reach of children.
- Do not use Dermol 500 Lotion after the expiry date shown on the container and carton, or after 18 months of first opening the container. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- After using the 500 ml bottle it is advisable to turn the top of the pump dispenser clockwise to lock it.

## 6. FURTHER INFORMATION

#### What Dermol 500 Lotion contains:

The **active ingredients** in this product are **benzalkonium chloride** (0.1% w/w), **chlorhexidine dihydrochloride** (0.1% w/w), **liquid paraffin** (2.5% w/w) and **isopropyl myristate** (2.5% w/w). The **other ingredients** are cetostearyl alcohol, macrogol cetostearyl ether (cetomacrogol 1000), phenoxyethanol and purified water.

#### What Dermol 500 Lotion looks like and contents of the pack

- The product is a white, non-greasy lotion that contains no dye or fragrance.
- This bottle contains 500 ml of lotion. The bottle is fitted with a pump dispenser. (50 ml 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** Aeropak, Viking Road, Great Yarmouth, NR31 0NU, UK.

**This leaflet was last revised in** July 2021.

## 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.

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 500 Lotion, 00173/0051.

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