

PACKAGE LEAFLET *Information for the user*
Dioderm 0.1% w/w Cream
hydrocortisone

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

Keep this leaflet. You may need to read it again. If you have any further questions, ask your doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours. If any side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT DIODERM IS AND WHAT IT IS USED FOR

- Dioderm is a medicine for application to the skin to treat eczema and dermatitis (areas of dry, red, inflamed, itchy skin).
- Dioderm is suitable for use by **adults, the elderly, children and infants**.
- The **active ingredient** in this product is hydrocortisone. This is one of a group of medicines called corticosteroids (which should not be confused with 'anabolic steroid' tablets or injections misused by some athletes).
- Corticosteroid creams, ointments and other topical preparations come in four different potencies or strengths. These are known as mild, moderately potent, potent or very potent. Healthcare professionals will usually refer to topical corticosteroid potency rather than strength. A potent or strong corticosteroid has a much stronger effect than a mild corticosteroid when using the same amount. The percentage of active ingredient that is sometimes included on product packaging does not indicate potency. Dioderm is classed as a mild corticosteroid. Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.
- The product works by reducing the redness, inflammation and itching associated with these skin problems.

2. BEFORE YOU USE DIODERM

Do not use Dioderm:

- If you are allergic (hypersensitive) to hydrocortisone or any of the other ingredients of Dioderm listed in Section 6;
- to treat any other skin problems, **especially skin infections**, as it may make them worse;
- on open wounds, ulcers or broken skin.

Take special care when using this product:

- Tell your doctor if at any stage you think any of the skin area being treated has become infected. Your doctor may advise you to stop using Dioderm for a while and start using an alternative anti-microbial treatment instead.
- Keep the product **away from the eyes**.
- Although hydrocortisone is generally regarded as safe, even for long term use, **do not use this product excessively**:
 - avoid using this product continuously or frequently for long periods (weeks or months on end);
 - this is especially important if you are using it over large areas, on the face or under airtight bandages or dressings;
 - **for infants and babies** it is very important not to over-use this product, so treatment should normally be limited to no longer than 7 days.
- If there is a worsening of your condition during use consult your prescriber – you may be experiencing an allergic reaction, have an infection or your condition may require a different treatment. If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using Dioderm without consulting your prescriber unless your prescriber has previously advised you to do so. If your condition has resolved and on recurrence the redness

extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.

- Contact your doctor if you experience blurred vision or other visual disturbances.

Using other medicines

Dioderm is not known to affect, or to be affected by, any other medicines.

Pregnancy and breast-feeding

It is unclear whether this product is safe for use during pregnancy and breast-feeding. Animal birth defects have occurred with similar medicines containing corticosteroids, so there may be a very small risk of these problems in humans.

You should therefore not normally use this product if you are pregnant or breast-feeding, unless your doctor has recommended you to do so.

Driving and using machinery

Using this product is not known to affect your ability to drive or use machinery.

Important information about one of the ingredients of Dioderm

The product contains a small amount of propylene glycol. This ingredient may cause skin irritation in a small number of people who are sensitive to it. If you have been told by your doctor that you are sensitive to propylene glycol, please talk to your doctor before using this product.

3. HOW TO USE DIODERM

Use Dioderm only on eczema and dermatitis. Before you use this tube of cream for the first time, unscrew the cap, turn it upside down and use the sharp point in the top of the cap to pierce the tube membrane.

For adults, the elderly and children:

- Apply Dioderm to the affected areas of skin **twice a day**.
- Gently massage the cream into the skin until it is absorbed.
- Always wash your hands after use.

When you can see that the skin condition is getting better, you can start to apply Dioderm **less often**, only once a day or even less. The frequency of application should be reduced to the minimum necessary to keep the skin condition under control.

For infants and babies (including in the treatment of nappy rash):

- Follow the above instructions for adults, but do not use continuously for longer than 7 days unless advised by a doctor.

If the cream accidentally gets into the eyes

it may cause irritation. If it gets into the eyes, rinse immediately 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 accidentally swallow some of the cream, it is unlikely to harm you but you should tell your doctor or pharmacist.

If you occasionally forget to use Dioderm, do not worry, 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, Dioderm can cause side effects, although not everybody gets them:

- In rare cases skin irritation (such as redness or itching) may occur. If this happens stop using the product.

- If your eczema or dermatitis seems to get worse during treatment, you may be allergic to one of the ingredients in the cream.
- Topical corticosteroids are usually well tolerated when used in the right amount and for the correct length of time. However, **prolonged, excessive use, particularly in children or on skin that is bandaged or wrapped up**, can cause local skin thinning (making the skin damage easily), striae (stretch marks) and adrenal suppression (a type of hormone imbalance that causes generalised effects on the body). Stopping treatment normally corrects these side effects.
- Steroid withdrawal reaction: If used over prolonged periods a withdrawal reaction, which might appear to be different from the previous condition, may occur in some patients during treatment or within days to weeks after stopping treatment, with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.
- Blurred vision.

If you experience any of the above, or if you experience any other side effect not mentioned in this leaflet, **stop using** this product and **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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DIODERM

- Keep out of the sight and reach of children.
- Do not use Dioderm after the expiry date shown on the fold of the tube and carton. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Always replace the cap tightly after use.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Dioderm contains:

The **active ingredient** is hydrocortisone (0.1% w/w). The **other ingredients** are citric acid, emulsifying wax, white soft paraffin, liquid paraffin, propylene glycol and purified water.

What Dioderm looks like and contents of the pack

- The product is a smooth, white cream.
- The product is available in tubes containing 30g, fitted with screw caps.

The Marketing Authorisation holder is:

Dermal Laboratories, Tatmore Place, Gosmore, Hitchin, Hertfordshire, SG4 7QR, UK.

The Manufacturer is: Fleet Laboratories Ltd, 94 Rickmansworth Rd, Watford, Hertfordshire, WD18 7JJ, UK.

This Patient Information Leaflet was last revised in September 2024.

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: Dioderm, 00173/0047. This is a service provided by the Royal National Institute of Blind People (RNIB).