

Adex™ Gel

Please read this entire leaflet carefully before you start using this product.

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

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

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1. WHAT ADEX GEL IS AND WHAT IT IS USED FOR

- Adex Gel is a highly moisturising and protective skin emollient which contains an ancillary anti-inflammatory medicinal substance.
- It helps in the treatment and routine management of dry and inflamed skin conditions such as mild to moderate atopic dermatitis, contact dermatitis, various forms of eczema and psoriasis in circumstances where ancillary anti-inflammatory action may be beneficial (e.g. during flares).
- Using it may help reduce reliance on more potent anti-inflammatory treatments such as corticosteroids and immunomodulators.
- Adex Gel is for use by adults, the elderly and children from 1 year of age.

2. BEFORE YOU USE ADEX GEL

Do not use Adex Gel if you are **allergic** (hypersensitive) to nicotinamide or to any of the other ingredients listed in Section 6.

Using medicines

This product is not known to affect, or to be affected by, medicines taken orally at the same time. It can also be used in addition to any other emollients or applied treatments your doctor, nurse or pharmacist may have given or prescribed for you to use to treat your dry skin condition. If you are using other topically applied products, follow the instructions in Section 3c below to avoid diluting the other product and spreading it to areas that do not need it.

Pregnancy and breast-feeding

Vitamin B derivative requirements, such as nicotinamide, are increased during pregnancy and infancy. However, safety trials have not been conducted during pregnancy and while breast-feeding. With prolonged use over significant areas, it may be possible to exceed the recommended levels of nicotinamide during pregnancy. Therefore caution should be exercised, particularly in the first three months of pregnancy. When breastfeeding, if use on the nipples is necessary, apply sparingly and after feeds. Gently wipe away any remaining product before feeding your baby. If you are uncertain, ask your doctor or pharmacist for advice before using this product.

Important Safety Information

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.

3. HOW TO USE ADEX GEL

This product is for generalised all-over application to the skin. Apply it three times daily or as often as needed.

- a. Before using the 500 g bottle, turn the top of the pump dispenser anti-clockwise to unlock it. After unlocking the first time, you will need to press down the pump dispenser several times to prime the pump before any product is dispensed.
- b. Gently smooth Adex Gel over and around all dry and inflamed skin areas. For best results, use a few gentle strokes to smooth the gel across the skin in the same direction as hair growth (like stroking a cat or dog). If necessary, allow time for any excess to soak in. Do not rub the skin vigorously.
- c. If you are using other topically applied products, any instructions supplied with the other product should be followed to allow adequate time for absorption before applying Adex Gel. The time allowed should normally be around 30 minutes for topical corticosteroids and up to 2 hours for certain calcineurin inhibitors. This is to avoid diluting the other product and spreading it to areas that do not need it.
- d. Carry on using Adex Gel for as long as necessary – whether that may be only occasionally, e.g. during flares, or continuously if the added anti-inflammatory action is beneficial. If there is no improvement within 2 to 4 weeks, ask your doctor or pharmacist for advice.

Take care when using this product:

When using it on your face, keep the gel away from your eyes, and avoid getting it inside your nostrils, on your lips or inside your mouth. Accidental eye contact may cause irritation and should be rinsed out with plenty of water. If rinsing one eye, take care to avoid washing product into the other eye. If eye irritation persists, tell your doctor or pharmacist.

If you forget to use Adex Gel

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

4. POSSIBLE SIDE EFFECTS

Although emollients are generally very helpful in treating dry skin conditions, they can sometimes be associated with temporary tingling, itching or stinging, especially where the skin is broken or scratched. Regular use of emollients can help to restore damaged skin, so occurrence of such symptoms may subside after a few days of emollient treatment. However, if such symptoms occur and are troublesome or persist for more than a few minutes, after application of Adex Gel, or do not subside once the gel has been used for several days, stop using the gel and, if necessary, consult your doctor, nurse or pharmacist for advice.

Although specially designed for use on problem skin, in rare cases this product may cause mild rashes or allergic skin reactions on extremely sensitive skin. These rare effects tend to occur during or soon after the first few uses.

Stop using this gel and **tell** your doctor, nurse or pharmacist:

- if your skin condition seems to look or feel worse;
- if any of the side effects get serious, or you notice any other side effects not mentioned in this leaflet.

If this product is accidentally **swallowed**, its oily ingredients may cause diarrhoea. If this happens:

- treat the symptoms as you would deal with any case of diarrhoea;
- drink plenty of water;
- do not attempt to cause vomiting.

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the manufacturer (see Section 6 below), or via: **United Kingdom:** Devices Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard; **Ireland:** HPRA Medical Devices Incident Reporting, website: www.hpra.ie. By reporting side effects you can provide more information on the safety of this product.

5. HOW TO STORE THIS PRODUCT

- Keep out of the sight and reach of children.
- Do not use the product after the use by date shown on the container and on the unit carton. The use by date refers to the last day of that month.
- Once opened, the product can be used until the use by date.
- Do not store above 25°C.
- Do not freeze the product.
- After using the 500 g bottle, it is advisable to turn the top of the pump clockwise to lock it. In the case of the tube, replace the cap after use.
- Occasionally, in the 500 g bottle a small pocket of air may form around the bottom end of the pump's dip tube, making it harder to pump the gel out. This may be resolved by tapping the base of the bottle firmly on a hard surface two or three times, so the gel can settle at the bottom around the end of the dip tube. The pump should then be pumped **slowly**.

6. FURTHER INFORMATION

What Adex Gel contains:

Carbomer, glycerol, isopropyl myristate 15%, liquid paraffin 15%, nicotinamide 4%, phenoxyethanol, sorbitan laurate, trolamine and purified water.

What Adex Gel looks like and contents of the pack

- The gel is available in a plastic tube containing 100 g or a plastic pump bottle containing 500 g. (25 g packs are also available to the medical and allied professions.)
- The product has the appearance of a white gel. It contains no dye or fragrance.

 **The Manufacturer is** Diomed Developments Ltd, Tatmore Place, Gosmore, Hitchin, Herts, SG4 7QR, UK.

 **The Importer in Ireland is** Allphar Services Ltd, 4045 Kingswood Road, Citywest Business Park, Co. Dublin, D24 V06K, Ireland.

 **The Distributor is** Dermal Laboratories Ltd, Tatmore Place, Gosmore, Hitchin, Herts, SG4 7QR, UK.

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7. GENERAL ADVICE ON USING EMOLLIENTS TO LOOK 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, as often as needed and even when the skin appears normal.
- 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.
- If you have eczema, 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 may not foam or lather very well but will be better for your dry skin condition.
- 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.



Medical Device



0459



Contains a Medicinal Substance



Consult Instructions for Use



Batch Code



Use-by Date



Manufacturer



Importer



Distributor