KEY INFORMATION – ADEX™ GEL

1 NAME OF THE PRODUCT

Adex Gel

2 PRODUCT TYPE

Emollient with an added ancillary anti-inflammatory medicinal substance

3 FORMULATION

White opaque gel
(For full list of ingredients see Section 6.1)

4 PRODUCT PARTICULARS

4.1 Product Claims

A highly moisturising and protective emollient which also 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 added to the primary emollient action may be beneficial (e.g. during flares). Such use may help reduce reliance on more potent anti-inflammatory treatments such as corticosteroids and immunomodulators.

4.2 Directions for Use

For use by adults, the elderly and children from 1 year of age.

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 to unlock it. After unlocking the first time, it will be necessary 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/or 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 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. Seek medical advice if there is no improvement within 2 to 4 weeks.

4.3 Contra-indications

Do not use in cases of known sensitivity to any of the ingredients.

4.4 Special Warnings and Precautions for Use

When using on the face, keep the gel away from the eyes, and avoid getting it inside the nostrils, on the lips or inside the 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. Seek medical advice if eye irritation persists. Accidental oral ingestion may cause diarrhoea, owing to the oily ingredients, which the leaflet advises should be treated symptomatically without attempting to induce vomiting.

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.

4.5 Interaction with other Products and other forms of Interaction

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 used to treat dry skin conditions.
If used in addition to other topically applied products, follow the instructions in section 4.2c to avoid diluting the other product and spreading it to areas that do not need it.

4.6 Pregnancy and Lactation

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. Seek medical advice from a doctor or pharmacist before using this product. 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.

4.7 Effects on Ability to Drive and Use Machines

None known.

4.8 Undesirable 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, patients should stop using the gel and, if necessary, consult their 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.

Patients should stop using this gel and tell their doctor, nurse or pharmacist:
• if their skin condition seems to look or feel worse;
• if any of the side effects get serious, or they notice any other side effects not mentioned in this leaflet.

Reporting of suspected adverse reactions
Reporting of suspect adverse reactions is important. It allows continued monitoring of the benefit/risk balance of the product. Healthcare professionals are asked to report any suspected adverse reactions either directly to the manufacturer (see section 7 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.

4.9 Overdose/abuse/misuse

Not applicable

5 MODE OF ACTION

The emollient ingredients help soften and protect the skin by trapping moisture and restoring the normal protective function of the skin. The ancillary medicinal substance, nicotinamide, is an anti-inflammatory related to vitamin (B_3), which helps reduce skin redness and inflammation.

6 QUALITY PARTICULARS

6.1 Ingredients

The ingredients are carbomer, glycerol, isopropyl myristate (15%), liquid paraffin (15%), nicotinamide (4%), phenoxyethanol, sorbitan laurate, trolamine, and purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

36 months

6.4 Special Precautions for Storage

Do not store above 25ºC. Do not freeze.

6.5 Nature and Contents of Container

500 g plastic bottle with pump dispenser or 100 g plastic laminate tube with screw cap.
25 g packs are also available to the medical and allied professions.
Individual sales packs comprise a unit carton containing one bottle/tube of gel and a Package Leaflet.

6.6 Special Instructions for Use, Handling and Disposal

No special requirements.

7 ECONOMIC OPERATORS

Distributor:	Dermal Laboratories Limited, Tatmore Place, Gosmore, Hitchin, Herts, SG4 7QR, UK
EUAR:	Acorn Regulatory Consultancy Services Limited, Knockmorris, Cahir, Co. Tipperary, E21 R766, Ireland
Importer (for ROI):	Allphar Services Limited, 4045 Kingswood Road, Citywest Business Park, Co. Dublin, D24 V06K, Ireland.
Manufacturer:	Diomed Developments Limited, Tatmore Place, Gosmore,Hitchin, Herts, SG4 7QR, UK

8 DATE OF PREPARATION/UPDATE

December 2022

BASIS FOR MARKETING
Class III medical device with an ancillary medicinal substance.