

BlephademoDEX®

This product is a medical device. Please read the instructions before use.

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

INDICATIONS

BLEPHADEMODEX is a sterile wipe, impregnated with a lotion for the daily hygiene of eyelids when there is Demodex blepharitis.

For use on the skin only, do not put directly into the eye.

SUITABLE FOR

Adults only.

CONTRAINDICATIONS

Do not use BLEPHADEMODEX if you are allergic to any of its ingredients (see Device Description).

In the absence of sufficient data, do not use

BLEPHADEMODEX if you are pregnant or breastfeeding unless advised by your doctor.

In the absence of sufficient data, BLEPHADEMODEX should not be used in children, unless advised by your doctor.

DEVICE DESCRIPTION

BLEPHADEMODEX is a sterile wipe, impregnated with a lotion.

The lotion contains: PEG-8, polysorbate 80, poloxamer 184, Terpinen-4-ol, PEG-6 caprylic/capric glycerides (Macrogol 6 glycerol caprylocaprate), sodium hyaluronate, dipotassium phosphate, potassium dihydrogen phosphate, purified water.

BLEPHADEMODEX is free from aggressive detergents and free from preservatives. BLEPHADEMODEX has a fresh scent due to natural ingredients; this dissipates a few minutes after application.

The color of the wipe may vary. This is due to the natural plant extracts (Terpinen-4-ol, a purified extract from tea tree oil) and is normal.

BENEFIT, PERFORMANCE AND MECHANISM OF ACTION

BLEPHADEMODEX is recommended:

- for daily hygiene of the eyelids when there is Demodex blepharitis,
- to relieve the symptoms of an eyelid infection or inflammation (blepharitis) caused by Demodex.

Demodex is the most common microscopic skin parasite but when there is an overload, irritating symptoms such as itching, burning, sore eyelids, redness on the lid margin and foreign body sensation can occur. The presence of eyelash dandruffs, which remain at the base of the lashes, is strongly indicative of a *Demodex* infection. *Demodex* mites are not removed by usual daily cleansing products and a dedicated treatment is required.

BLEPHADEMODEX cleans away crusts, eyelash dandruff, impurities and infectious agents on eyelids and eyelashes. BLEPHADEMODEX improves symptoms linked to *Demodex* infection, such as itching, burning, dryness and lid margin inflammation. Eyelid redness and foreign body sensations are reduced.

The wipe contains sodium hyaluronate, a natural moisturising agent, which soothes and regenerates sensitive skin.

BLEPHADEMODEX is well tolerated.

The product has been tested under ophthalmological control.

GENERAL RECOMMENDATIONS FOR USE

Dosage:

- Mild to moderate symptoms: Use once a day, preferably in the evening for 4 weeks.
- Moderate to severe symptoms: Use twice a day, morning and evening for 4 weeks.

Your healthcare professional may adapt the posology and the duration of treatment according to the severity of symptoms.

As per other similar blepharitis treatments, the concomitant use of artificial tears might be recommended by your healthcare professional.

BLEPHADEMODEX is easy to use.

If you wear contact lenses: you must remove them before using BLEPHADEMODEX.

Wash hands thoroughly before using the wipes.

Tear across the sachet to open (Figure 1) and unfold the wipe inside; do not use any tool to open the sachet.



Figure 1: Opening the sachet

Wrap the wipe around the top of your index finger.

Keeping your eye closed, carefully place the wipe on your eyelids and the base of the eyelashes (Figure 2).

Gently massage with small circular movements, removing any crusts or secretions.



**Figure 2:
Cleansing your eyelids and eyelashes**

Repeat on the other eye, using a new wipe.

BLEPHADEMODEX is non-greasy and does not need to be rinsed after use.

Keep your eye closed for 15 seconds after use.

CAUTIONS FOR USE

Check the packaging is intact before first use: use only if the sachet is unopened.

Do not use any wipe more than once, as it may not work as well and may cause contamination.

You must contact a healthcare professional if your symptoms get worse or do not improve.

WARNINGS

Keep out of the sight and reach of children.
Avoid getting BLEPHADEMODEX into the eyes, you may experience a burning sensation. If this happens, rinse with sterile water or saline solution.

SIDE EFFECTS

The following side effect has been reported: burning sensation after use.
In such cases, contact lens wearers should not put their contact lenses back in.
If you notice any side effects or unusual sensations after using this product, please contact a healthcare professional and report the information to the local distributor, to the manufacturer or to your local Health Authority (see contacts at the end of the instructions for use).

STORAGE AND DISPOSAL CONDITIONS

Store between 8°C and 25°C.
Do not expose your product to direct sunlight or humidity.
Throw away the wipe immediately after use.
Do not use after the expiry date clearly marked on the sachet and outer carton.
The expiry date refers to the last day of that month as long as the packaging is intact and it has been stored correctly.
Dispose of the product responsibly and in accordance with local guidance (the sachet and the wipe should be disposed of as household waste, the outer carton and the leaflet are recyclable).

Date of issue and version of the instruction for use:
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Manufacturer:



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« Contact us » section

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Distributor:

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www.thea-pharmaceuticals.co.uk
0345 521 1290

Health authority:

Medicines and Healthcare products Regulatory Agency,
10 South Colonnade, London, E14 4PU
020 3080 6000

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Distributor:

THEA Pamex Ltd, 14 Moneen Business Park, Castlebar, Co. Mayo
0 94 92 50290

Health authority:

Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, D02 XP77
1 676 4971

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MEANING OF THE PICTOGRAMS ON THE PACKAGING

| | |
|--|----------------------------------|
| | Manufacturer |
| | Batch number |
| | Date of manufacture |
| | Use-by date |
| | Temperature limits |
| | Sterilized using irradiation |
| | Medical Device |
| | Consult instruction for use |
| | Single use |
| | Do not use if package is damaged |
| | Caution |

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