

Blephaclean®

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

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

INDICATIONS

BLEPHACLEAN is indicated for the daily hygiene of eyelids. For use on the skin only, do not put directly into the eyes.

SUITABLE FOR

- Adults,
- Children over 3 months: Parents or carers should administer the product.

CONTRAINDICATIONS

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

In the absence of sufficient data, do not use BLEPHACLEAN if you are pregnant or breastfeeding unless advised by your doctor.

DEVICE DESCRIPTION

BLEPHACLEAN is a sterile wipe, impregnated with a lotion for the daily hygiene of eyelids.

The lotion contains: capryloyl glycine, sodium hyaluronate, PEG 8, poloxamer 184, polysorbate 20, propylene glycol, hydrocotyl extract (propylene glycol, centella asiatica extract and water), preservative-free Sebum-regulating complex (propylene glycol, Iris florentina root extract, zinc sulphate, PPG-5 Ceteth 20 and Retinyl palmitate (Vitamin A), alcohol and water), PEG 6 caprylic/capric glycerides (i.e. Macrogol 6 glycerol caprylocaprate), dipotassium phosphate, sodium hydroxide, potassium dihydrogen phosphate, purified water.

The colour of the wipe may vary. This is due to natural plant extracts and is normal.

BENEFIT, PERFORMANCE AND MECHANISM OF ACTION

BLEPHACLEAN is a sterile wipe for daily eyelid hygiene especially:

- When you have sensitive skin, eyelids or eyes;
- When you need to remove dust, pollen and discharge from your eyelids. This could be part of your care when you have allergy or infection in your eyes;
- When you have inflammation or infection of the eyelids such as blepharitis, Meibomian gland dysfunction, styes or chalazion. These conditions can cause dry eye symptoms like itchy, gritty, sore and/or red eyes;
- When you need to clean your eyelids before ophthalmic procedures such as therapeutic injections into your eye (intra-vitreous injections), refractive laser eye surgery (LASIK or PRK) and cataract surgery. Because it is well tolerated, BLEPHACLEAN can also be used after surgery, based on the advice from your doctor or ophthalmologist.

BLEPHACLEAN cleans and removes dust, pollen and discharge from the eyelids. BLEPHACLEAN respects the skin around the eyes and its natural bacteria.

The product has been tested under ophthalmological control.

GENERAL RECOMMENDATIONS FOR USE

Dosage:

Before eye surgery, use **twice a day** for 5 days or as your doctor or pharmacist tells you to.

For other cases, use **twice a day** in the morning and evening for 3-weeks and then once a day for 3 months or as your doctor or pharmacist tells you to. Some eyelid conditions are chronic and you may need to continue eyelid hygiene long term.

BLEPHACLEAN is easy to use.

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

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, secretions or make-up.



Figure 2: Cleansing your eyelids and eyelashes.

In front of a mirror, gently pull your lower eyelid down with your other hand and then rub your finger with the wipe wrapped around it along the edge of your lower eyelid (Figure 3).

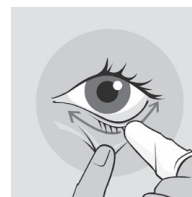


Figure 3: Cleansing the eyelid margin.

Repeat on the other eye, using a new wipe.

There is no need to rinse after using BLEPHACLEAN wipes.

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 BLEPHACLEAN into the eyes; you may experience a burning sensation. If this happens, rinse with sterile water or saline solution.

SIDE EFFECTS

The following events have been reported with BLEPHACLEAN: burning or itching sensation for some minutes after use, redness or swelling of the eyelids, ocular redness, allergic reactions.

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 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:

Ver. 2 09/2019

Manufacturer:



Laboratoires Théa
12 rue Louis Blériot
63017 Clermont-Ferrand
Cedex 2 France

www.laboratoires-thea.com

« Contact us » section

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Distributor:

THEA Pharmaceuticals Ltd, MED IC5, Innovation Way,
Keele University Science and Innovation Park, Keele,
Newcastle Under Lyme, Staffordshire, ST5 5NT
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

IE

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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