

INSTRUCTIONS FOR USE

BLEPHA EyeBag®

This product is a medical device.
Please read the instructions carefully before use. Keep this leaflet.
You may need to read it again.

1. INDICATIONS

BLEPHA EYEBAG is a reusable warming mask.
BLEPHA EYEBAG treats Meibomian Gland Dysfunction* (MGD) and Blepharitis.
It provides comfort and relieves symptoms of dry eye associated with MGD (MGD is the leading cause of dry eye) and other related eye-conditions such as:

- Stye
- Chalazion

BLEPHA EYEBAG may also relieve discomfort related to contact lenses worn by patients suffering from dry eyes.

Ocular use only.

2. SUITABLE FOR

- Adults (including pregnant or breastfeeding women),
- Children from the age of 3 years old: parents or carers should handle the product.

3. CONTRAINDICATIONS

Do not use **BLEPHA EYEBAG** if the skin around the eyes is broken or bleeding.
Do not use **BLEPHA EYEBAG** on your face if you have a known hypersensitivity to flax, linseed or any of the other constituents of **BLEPHA EYEBAG**.

4. DEVICE DESCRIPTION

BLEPHA EYEBAG is a handmade and patented re-usable eye mask made of natural silk and cotton, filled with untreated flax (linseed). It contains no other additives and no plastic. **BLEPHA EYEBAG** is also eco-friendly as its carton and leaflet are biodegradable and recyclable.

5. BENEFIT, PERFORMANCE AND MECHANISM OF ACTION

In the edges of the upper and lower eyelids there are small glands, the Meibomian glands, which secrete an oily substance needed to lubricate and clean the front of the eye, and to allow the tear film to spread effectively.
When the glands are not functioning normally the oil turns to a thick grease and clogs up the glands. This means the front of the eye is not well lubricated. Ophthalmologists recommend warming the eye as the first step of an eyelid cleansing routine in cases of MGD, blepharitis and the related conditions such as dry eye, chalazion and stye.
By its warming action, **BLEPHA EYEBAG** contributes to a natural and healthy eye by helping to release the blocked lipids and allowing them to spread across the eye surface. By doing so it reduces water evaporation to keep the eyes hydrated.
BLEPHA EYEBAG acts quickly and is long-lasting to relieve symptoms such as dry eye sensation, eye discomfort, tired or sore eyes, red eye, grittiness, foreign body sensation and stinging. It also soothes swollen and inflamed eyelids.
BLEPHA EYEBAG was developed by an ophthalmologist and its safety and effectiveness has been proven in several clinical studies.
BLEPHA EYEBAG is an easy-to-use and pleasant warming mask that can be used on a daily basis to make the eye(s) feel comfortable.

6. GENERAL RECOMMENDATIONS FOR USE

BLEPHA EYEBAG is easy to use.
If you wear contact lenses or prescription glasses, always remove them before using **BLEPHA EYEBAG**.

Carefully wash your hands, face, eyelids and remove makeup before using **BLEPHA EYEBAG**.

POSIOLOGY: For the first 2 weeks use your **BLEPHA EYEBAG** twice a day, morning and evening, for 5 to 10 minutes each time. After the first 2 weeks 3 to 4 times a week is usual, but you can adjust the frequency of use according to the severity of your symptoms.

BLEPHA EYEBAG is safe and efficient to use **up to 200 times** before it must be replaced.

GENERAL RECOMMENDATIONS
Before using **BLEPHA EYEBAG**, ensure that it has no defects.
BLEPHA EYEBAG should only be warmed by a responsible adult.
Remove **BLEPHA EYEBAG** from the box and place it on a clean, dry and microwaveable plate. Always make certain the dish or plate you use is completely clean as any small food residue can become very hot and these "hot spots" might cause small burns in **BLEPHA EYEBAG** material.

BEFORE FIRST USE

Place **BLEPHA EYEBAG** in a microwave as described above.
Heat your **BLEPHA EYEBAG** for 1 minute on full power in a good working microwave and **leave to cool completely**.

FOR ALL FURTHER USES

Step 1: Place **BLEPHA EYEBAG** in a microwave as described above and heat according to the table below:

POWER of the microwave	HEATING DURATION
Above 750 W	30 seconds
750 W and below	40 seconds

Caution: If your microwave is greater than 1000 W, you may need to reduce the time.
Only reheat from room temperature.
Further heating a **BLEPHA EYEBAG** which is already hot can be dangerous and lead to overheating. Allow the **BLEPHA EYEBAG** to cool fully before reheating.

⚠ Make certain you only set for 30 seconds, and not 30 minutes! Stay by your microwave while it is heating. **Do not use the metal griddle supplied with some microwaves as this may burn your BLEPHA EYEBAG.**

Step 2: Shake the **BLEPHA EYEBAG** to evenly spread the linseeds inside the mask and to help the heat to spread.

Step 3: Check **BLEPHA EYEBAG** is comfortably warm but not too hot **before** placing it over the closed eyelids. Carefully check the temperature on the grey (silk) side by touching **BLEPHA EYEBAG** with your wrist. If it is too hot, wait a few minutes and check the temperature again before applying to the eyes.

Step 4: When the temperature is comfortably warm, lie back and apply the mask on closed eyes. Use either side according to preference. Relax with **BLEPHA EYEBAG** in place for 5 to 10 minutes.
The black side will be cooler, and you may wish to switch to the silk side during the course of the 10 minutes.

Step 5: Remove **BLEPHA EYEBAG** from your eyes. It is normal to observe skin redness after use due to the warming effect of the mask.

Step 6: Immediately after warming, massage the closed eyelids to release the oil from the Meibomian glands. Repeat this several times for about 30 seconds

Example of a massage technique

Step 7: You can also cleanse your eyelids with an eyelid cleansing product and gently massage them, after the use of **BLEPHA EYEBAG**.

Step 8: Always put **BLEPHA EYEBAG** back in its box after use to keep it clean, dry and safe.

Each microwave heating minimises the amount of bacteria on the **BLEPHA EYEBAG**.

7. CAUTIONS FOR USE

Check the packaging is intact before first using this product.
Before using **BLEPHA EYEBAG**, ensure that there are no defects.
Make sure you use a serviceable and properly functioning microwave to heat your **BLEPHA EYEBAG**.
Each **BLEPHA EYEBAG** should only be used by one person.
To prevent cross contamination do not share **BLEPHA EYEBAG** between different people.
You must contact a healthcare professional if your symptoms persist or worsen with **BLEPHA EYEBAG** use.

8. WARNINGS

Keep out of the sight and reach of children.
Always use your **BLEPHA EYEBAG** according to these instructions.
It is usual for **BLEPHA EYEBAG** to feel slightly moist on first use.
Carefully check the temperature before use.
If you have other specific eye conditions (such as a corneal dystrophy or recurrent corneal infections) you should use **BLEPHA EYEBAG** cautiously and follow the advice of your eye health professional.
If you have rosacea, heat may increase redness. Use with caution.
The linseeds contained in your **BLEPHA EYEBAG** are not food grade and should not be ingested.

Heating a wet **BLEPHA EYEBAG** may cause scalding.

9. HOW TO TAKE CARE OF YOUR BLEPHA EYEBAG

Do not wash or wet your **BLEPHA EYEBAG** (detergents and washing powders may cause irritant contact dermatitis).
Stains on the surface of **BLEPHA EYEBAG** after use are normal and harmless.
Wet wipes should not be used to clean the surface of **BLEPHA EYEBAG**.

10. SIDE EFFECTS

The following side effects may be observed: eye/eyelid irritation, pain, redness and itchiness.
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).

11. STORAGE AND DISPOSAL CONDITIONS

Store your **BLEPHA EYEBAG** in its box in a clean, dry place.
Your **BLEPHA EYEBAG** should be replaced after 6 months if used once a day.
Dispose of the product responsibly and in accordance with local guidance (the device should be disposed of as household waste; the outer carton and the leaflet are biodegradable and recyclable).

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Manufacturer:
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0345 521 1290
Health authority: Medicines and Healthcare products Regulatory Agency, 10 South Colonnade, London, E14 4PU
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Distributor: Thea Pharma Ltd, Golden Mile Industrial Park, Braffay Road, Castlebar, Co Mayo, F23D299
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12. SET-UP AN EYE ROUTINE FOR HEALTHY EYES & EYELIDS

A daily eye care routine is recommended by experts to keep the eyes and the eyelids healthy if you have dry eye associated with MGD.

1. EYELID CLEANSING

The eyelid cleansing regime is composed of 3 steps:

- **Step 1: Warming**
Heat melts the blocked lipids in the gland to allow the tear film to spread effectively.
- **Step 2: Massage**
Massage the eyelids to help remove the meibum in clogged glands.
- **Step 3: Cleanse**
Cleanse the eyelids and eyelashes to remove secretions, deposits or crusts using a suitable eye-care product.

2. HYDRATING

Ideally with preservative-free eye drops to keep the eye hydrated and comfortable during the day.

13. MEANING OF THE PICTOGRAMS ON THE PACKAGING

	Manufacturer		Consult instruction for use
	Batch number		Single patient - Multiple use
	Date of manufacture		Medical Device
	Keep dry		Caution
	Catalogue number		Use by date
	Do not use if package is damaged		

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