HYABAK®

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

1. INDICATIONS

HYABAK is intended to moisten and lubricate the surface of your eyes if they feel dry or tired.
HYABAK is also intended to lubricate the contact lens when your lenses feel uncomfortable.
For ocular use only.

2. SUITABLE FOR

- Adults,
- Children: Parents or carers should apply the drops,
- Pregnant or breastfeeding women based on current knowledge,
- Wearers of any type of contact lenses.

Please note that two different **HYABAK** products are available worldwide. You are currently using the product T1557, as stated on the outer carton. If you purchase **HYABAK** abroad, make sure that the product that you buy is suitable for you. Please read the contraindications carefully before use.

3. CONTRAINDICATIONS

Do not use **HYABAK** if you are allergic to any of the ingredients (see Device description).

4. DEVICE DESCRIPTION

HYABAK is an eye-drop solution containing hyaluronic acid (as sodium hyaluronate 0.15%), sodium chloride, trometamol, hydrochloric acid and water for injections.

HYABAK is a sterile, phosphate-free, isotonic and pH neutral solution.

The solution is supplied in the ABAK® multi-dose bottle. This innovative and patented design delivers eye drops through a 0.2 µm filter, preventing any bacterial contamination of the solution and avoiding the use of any preservatives. Therefore, **HYABAK** is gentle for the eyes as it is preservative-free. The absence of preservatives allows the ocular tissue to be protected and does not cause reactions in people who are sensitive to preservatives.

5. BENEFIT, PERFORMANCE AND MECHANISM OF ACTION

HYABAK is recommended for moistening and lubricating the eye if you have dryness or tired eyes caused by wind, smoke, pollution, dust, dry heat, air conditioning, air travel, or prolonged work in front of a computer screen/digital device. It provides immediate relief and makes the eyes feel more comfortable during the day.

HYABAK is also recommended for contact lens wearers. It lubricates and hydrates the lens, helping with putting contact lenses in and taking them out, as well as allowing them to be worn all day long.

The main ingredient of **HYABAK** is hyaluronic acid (as sodium hyaluronate), a natural polysaccharide found in the human eye which retains water to hydrate and lubricate the surface of the eye. It keeps the solution on the surface of the eye, giving long lasting relief and reducing the healing time of the surface of the eye.

6. GENERAL RECOMMENDATIONS FOR USE

There is no particular training required to use **HYABAK**.

Wash hands thoroughly before use.
Do not use any tool to open the bottle.
When you first use **HYABAK**, you will find the first drop takes longer to come out due to the unique filtration system in the bottle (see device description).
Replace the bottle cap after use.

To moisten and lubricate the eye:
Dose: 1 drop in each eye, as often as necessary during the day.
Apply one drop to the inside of the lower eyelid, while gently pulling the lower lid down and looking up. Close the eye gently after application.



To lubricate and hydrate the lens:
Dose: 1 drop on each lens when putting them on or removing them, as well as often as necessary during the day.
Before placing your contact lens, simply apply a drop into the inside of the lens when it is on your finger.
Put your lens in as usual and blink a few times to allow the solution to settle, ensuring an even distribution of **HYABAK** over the eye and the surface of the contact lenses.



7. CAUTIONS FOR USE

Multiple use product for single patient.
Do not share bottles with others to prevent cross contamination.
Check that the packaging is intact before first using this product.
Check that the tamper-proof ring on the bottle is intact before using it for the first time.
To avoid contamination, do not allow the tip of the bottle to touch anything.
You must contact a healthcare professional if your symptoms get worse or do not improve.

8. WARNINGS

Keep out of the sight and reach of children.
Do not inject and do not swallow.
After use, do not drive or use machines if your vision is blurred: wait for a few minutes until your vision clears.
Wait at least 10 minutes before using different eye products.
Never dilute **HYABAK** or mix it with other solutions.
If exposed to low atmospheric pressure (such as on an airplane), the bottle may leak after the first use.

9. SIDE EFFECTS

The following side effects have been reported: rare possibility of eye irritation, allergic reactions, eye pain, foreign-body sensation, blurred vision and ocular redness. In such cases, contact lens wearers should remove their contact lenses.

When you use eye drops, you might experience disturbing symptoms such as a burning sensation in the eye or a stinging sensation in the eye for a short time.

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, the manufacturer, or your local Health Authority (see contact details at the end of the instructions for use).

10. STORAGE AND DISPOSAL CONDITIONS

Store between 8°C and 30°C.
Do not expose your product to direct sunlight or humidity.
Do not use after the expiry date, given on the bottle and on the outer box.
The expiry date refers to the last day of that month as long as the packaging is intact and has been stored correctly.
The product can be used for 6 months after it has first been opened. After this time, discard any leftover product responsibly.
Dispose of the product responsibly and in accordance with local guidance (the bottle should be disposed of as household waste; the outer carton and the leaflet are recyclable).

Thea
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Manufacturer:

Laboratoires Théa
12 rue Louis Blériot
63017 Clermont-Ferrand
Cedex 2 France
www.laboratoires-thea.com
« Contact us » section

UK

Distributor:

THEA Pharmaceuticals Ltd, MED IC5,
Innovation Way,
Keele University Science and Innovation Park, Keele, Newcastle Under Lyme, Staffordshire, ST5 5NT, UK
www.thea-pharmaceuticals.co.uk
Tel.: 0345 521 1290

Health authority:

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

11. MEANING OF THE PICTOGRAMS ON THE PACKAGING

	Manufacturer
	Consult instruction for use
LOT	Batch code
	Single patient – Multiple use
	Date of manufacture
MD	Medical Device
	Keep dry
	Caution
+30°C +8°C	Temperature limit
	Keep away from sunlight
	Use-by date
UDI	Unique device identifier
STERILE A	Sterilized using aseptic processing techniques
REF	Catalogue number
	Do not use if package is damaged and consult instructions for use
	Single sterile barrier system with protective packaging outside