

Hyabak®

This product is a medical device.

Please read the instructions before use.

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

INDICATIONS

HYABAK is indicated to moisten and lubricate the surface of your eyes and contact lenses.
For ocular use only.

SUITABLE FOR

- Adults only,
- Wearers of any type of contact lenses.

CONTRAINDICATIONS

Do not inject and do not swallow. Do not use HYABAK if you are allergic to any of its ingredients (see Device description).

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

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

DEVICE DESCRIPTION

HYABAK is an eyedrop solution containing sodium hyaluronate (0.15%), sodium chloride, actinoquinol, trometamol, hydrochloric acid and water for injections.

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

The solution is supplied in the patented ABAK® multi-dose bottle. This innovative design delivers eye drops through a 0.2 µm filter, preventing any bacterial contamination of the solution and avoiding the use of any preservatives.

This means HYABAK is gentle for eyes because it is preservative-free. Avoiding chemical preservatives is beneficial for the eye's delicate surface long term and eliminates reactions amongst people who are sensitive to preservatives.

BENEFIT, PERFORMANCE AND MECHANISM OF ACTION

HYABAK is recommended to moisten and lubricate the eyes if you have dryness sensations or tired eyes caused by external factors such as 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, facilitating placement or removal and comfort when wearing your lenses.

The main ingredient of HYABAK is sodium hyaluronate, a natural polysaccharide which holds water to hydrate and lubricate the surface of the eye. It keeps the solution on the surface of the eyes giving long lasting relief and improving the rate of healing.

HYABAK contains also actinoquinol (agent with anti-UV properties).

GENERAL RECOMMENDATIONS FOR USE

HYABAK is easy to use.

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:

Dosage: 1 drop in each eye, as often as necessary during the day.

Apply one drop in the pocket of the eyelid, while gently pulling the lower lid down and looking up. Close the eye gently after application.



To lubricate and hydrate the lens:

Dosage: 1 drop on each lens when putting on and removing them, and also as often as necessary during the day.

Before applying 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 the eye 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.



CAUTIONS FOR USE

Multi-dose bottle, for use by one person only.

Do not share bottles between different people to prevent cross contamination.

Check the packaging is intact before first using this product.

Check the tamper-proof ring on the bottle is intact before using it for the first time.

To avoid contamination, do not touch the tip of the bottle with anything.

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.

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 between using two different eye products. Never dilute HYABAK or mix it with other solutions.

Once opened, if you expose the bottle to low atmospheric pressure (such as on an airplane), the bottle may leak.

The UV filter does not replace the wearing of sunglasses.

SIDE EFFECTS

The following side effects have been reported: rare possibility of mild eye irritation 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 burning sensation, stinging sensation, foreign body sensation in the eye and blurred vision 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, 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 30°C.

Do not expose your product to direct sunlight or humidity.

Do not use after the expiry date, which is marked 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 it has been stored correctly.
The product can be used until 3 months after first opening. 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).

Date of issue and version of the instructions for use :
Ver.3 11/2019

Manufacturer:

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

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
Tel.: 020 3080 6000

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 XF77
Tel.: 1 676 4971

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REF T1552

**MEANING OF THE PICTOGRAMS
ON THE PACKAGING**

	Manufacturer
	Medical Device
	Batch number
	Consult instruction for use
	Date of manufacture
	Single patient – Multiple use
	Use-by date
	Do not use if package is damaged
	Temperature limits
	Caution
	Sterilized using aseptic processing techniques
	Catalogue number