

OFTEA

OFTEA is an ophthalmic, isotonic, sterile saline solution.

Thanks to its particular formulation, OFTEA has a refreshing, moisturizing and soothing action that relieves common symptoms of eye dryness such as conjunctival hyperemia (red eye), foreign body sensation (feeling of sand in the eye) and blurred vision.

The sodium chloride in the solution ensures an isotonic saline solution while Green Tea, Chamomile, Witch Hazel and Eyebright distilled waters contribute to the moisturizing action.

The solution also contains boric acid and sodium tetraborate as a buffer system to ensure compliance with physiological pH of the ocular surface and benzalkonium chloride as a preservative.

OFTEA is indicated in adults (18-64 years).

INTENDED USE

OFTEA is indicated for refreshing and soothing the eye in case of ocular discomfort due to:

- environmental factors (air conditioning, excessive exposure to sun, wind, smoke, dust, sea water);
- excessive eye fatigue due to long-term computer use, studying or dry eye syndrome;
- use of contact lenses for many hours a day.

INSTRUCTIONS FOR USE

- Wash and dry your hands thoroughly before use;
- Before use the product for the first time, firmly unscrew the protective cap to break the guarantee seal;
- Open the bottle by turning the protective cap anticlockwise;
- Remove the protective cap;
- Turn the bottle upside down and apply gentle pressure to instill 1 or 2 drops into the eye;
- After use, immediately close the container by turning the protective cap clockwise.

COMPOSITION

Green Tea Distilled Water (*Camellia sinensis*) 8%, Chamomile Distilled Water (*Chamomilla recutita*) 8%, Witch Hazel Distilled Water (*Hamamelis virginiana*) 8%, Eyebright Distilled Water (*Euphrasia officinalis*) 8%, boric acid, sodium tetraborate decahydrate, sodium chloride 0,08%, EDTA, benzalkonium chloride, water for injections. It contains preservatives.

WARNINGS AND PRECAUTIONS

- Due to benzalkonium chloride, do not use in case of eye diseases (e.g. glaucoma, Leber hereditary optic neuropathy).
- The product contains the following CMR substances in concentrations above than 0.1% w/w: boric acid and sodium tetraborate decahydrate. The product is not suitable for children, pregnant or lactating women.
- This product must not be used more than 4 times a day.
- Remove contact lenses before using this product. After use, wait at least 15 minutes before reinserting the lenses.
- The product is for ophthalmic use only.
- The product is for single patient use only.
- Do not use it if the guarantee seal on the bottle cap is broken.
- During applications do not touch the eye or any other surface with the end of the dispenser.
- Do not use in case of known incompatibility with any component of the preparation and/or in case of allergies to plants of the Asteraceae and/or Compositae and/or Hamamelidaceae family.
- Do not use the eye drops for longer than 28 days after first opening the bottle. Discard 28 days after opening, even if there is a solution remaining.
- No interactions with drugs or other eye drops are reported; however, leave at least 15 minutes between administrations of any other eye drops.
- Do not use the product after the expiry date indicated on the carton and bottle.
- If any undesirable effects occur during use, discontinue use and consult a doctor.
- Keep out of the reach and sight of children.
- Dispose of this product according to your local waste management regulations.
- For external use only. Do not swallow.
- Do not tamper with the bottle dispenser.
- It is necessary to report any serious incident occurred in relation to the device to the manufacturer and the Competent authority of the Member state in which you are established.

SIDE EFFECTS

No undesirable side-effects are known so far.

STORAGE CONDITIONS

Store at room temperature (15°C – 25°C).

PACKAGING

One bottle of 10 ml.

VALIDITY

When unopened, do not exceed the expiry date indicated on the carton and bottle.

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MD

STERILE A

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DT/01/DT/013



C.O.C. Farmaceutici S.r.l.

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Distributor's address:

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