

IMPORTANT: Please read carefully and keep this information for future use.

Eyedia Multi-Purpose Contact Lens Solution



Symbols key

The table shows the symbols that may appear on label or carton

Symbol	Description
	Sterilized using aseptic processing techniques
	Single sterile barrier system
	Caution
	Consult instructions for use
	Do not use if package is damaged and consult instructions for use
	Do not resterilize
	Medical Device
	Use by date (Expiry date)

Symbol	Description
	Keep away from sunlight
	Temperature limits
	Manufacturer
	European conformity sign
	Authorized Representative in European Community
	Model number
	Unique Device Identifier
	Batch code (Lot number)
	European conformity sign



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DESCRIPTION:

Eyedia Multi-Purpose Solution is a sterile, isotonic, buffered aqueous solution that contains Sorbitol, Tromethamine, Tyloxapol and Disodium Edetate, preserved in 0.00011% Polyhexamethylene Biguanide.

INDICATIONS (USES):

Eyedia Multi-Purpose Solution is indicated for daily cleaning, rinsing, disinfecting, surface conditioning, removal of proteins and lipid deposits, and storage of soft (hydrophilic) contact lenses, including silicone hydrogel contact lenses, as recommended by your eye care practitioner.

PATIENT TARGET GROUPS:

The patient target groups for the use of **Eyedia Multi-Purpose Solution** are adults of 18 years or older. There is no clinical data to support the use of this device by individuals under 18 years of age. Use of this device by individuals less than 18 years of age is at the sole discretion of the eye care professionals (ECP).

INTENDED USERS:

Eyedia Multi-Purpose Solution is intended for users of re-usable soft contact lenses.

CONTRAINDICATIONS (REASONS NOT TO USE):

If you are allergic to any ingredient in this product, do not use.

DO NOT USE **Eyedia Multi-Purpose Solution** when any of the following conditions are present:

- Acute and subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- Severe insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic.
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lens.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lens or use of contact lens solutions.
- Any active corneal infection (bacterial, fungi, or viral).
- If eyes become red or irritated.
- If the patient is unable to follow lens care regimen or unable to obtain assistance to do so.

DIRECTIONS FOR USE:

To open the bottle for the first time, screw in the cap until the tamper evident ring breaks off. The cone pin inside the cap will puncture the bottle tip.

When you remove your contact lenses:

1. Wash and dry hands prior to handling your contact lenses.
2. Place 3 or more drops of **Eyedia Multi-Purpose Solution** on each side of the lens surface and gently rub each side of the lens from the centre to the edges for 10 seconds (Never rub in a circular motion because it may tear the lens and not clean the outer edge surfaces).
3. Thoroughly rinse each side of the lens for 5 seconds with **Eyedia Multi-Purpose Solution**.
4. Place cleaned contact lenses in the lens case and fill with fresh **Eyedia Multi-Purpose Solution**. Close the lens case tightly. Always use fresh solution – discard solution from lens case after each use.
5. Allow lenses to soak for at least 6 hours.
6. Prior to reapplying lenses, rinse each side of the lens for 5 seconds with **Eyedia Multi-Purpose Solution** to remove any debris on the lens.

LENS STORAGE

If not wearing contact lenses immediately, store in closed lens case. You may leave your lenses in the unopened lens case containing **Eyedia Multi-Purpose Solution** and replace with fresh solution every 30 days to store lenses for longer time. Repeat steps 1 to 6 described above to clean and disinfect your lenses before wearing lenses again.

New contact lenses are supplied in a sterile state by contact lens manufacturers. There is **NO NEED** to rinse new contact lenses upon removal from a sterile blister package. If you choose to treat new contact lenses with **Eyedia Multi-Purpose Solution** prior to insertion, rinse each side of the lens for 5 seconds and soak lenses in closed lens case with fresh **Eyedia Multi-Purpose Solution** for 10 minutes, then rinse each side of the lens for 5 seconds.

WARNINGS:

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN CORNEAL INFECTION AND/OR ULCER AND LEAD TO LOSS OF VISION. It is essential to follow your eye care practitioner’s directions and all labelling instructions for proper use of your lenses and lens care products, including the lens case.

- Do not expose or store your lenses in or rinse your lens case with any water, such as tap, bottled, or distilled, or with any non-sterile solution.
- Never use water, saline solution, or rewetting drops to disinfect your lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.

- Always wash and dry hands before handling lenses.
- Rub, rinse and soak your lenses for the recommended amount of time to help prevent serious eye infection.
- Always use fresh solution every time you clean, disinfect, and store your lenses. Never reuse the solution or add fresh solution to used solution.
- Lens case can be a significant source of microbial contamination. Always empty the lens case, rinse with fresh solution, and allow to air dry after lenses have been removed from lens case.
- To avoid contamination, do not touch the tip of the bottle to any surface.
- Do not transfer, mix or dilute the solution to other bottles or containers.
- Do not mix the solution with other solutions.
- Do not use with heat (thermal) disinfection.

Daily wear lenses are not indicated for overnight wear and should not be worn while sleeping. Extended wear lenses should be regularly removed for cleaning and disinfection or for disposal and replacement on the schedule prescribed by your eye care professional. If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, immediately remove your lenses and promptly contact your eye care practitioner. It is recommended that contact lens wearers visit their eye care practitioner twice each year, or if directed, more frequently.

ADVERSE REACTIONS:

The following problems may occur:

- Eyes sting
- Burn or itch (irritation)
- Comfort is less than when lens was first placed on the eye
- Feeling of something in the eye (foreign body, scratched area)
- Excessive watering (tearing) of the eye
- Unusual eye secretions
- Redness of the eye
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision
- Rainbows or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

If you notice any of the above: **IMMEDIATELY REMOVE YOUR LENSES.**

1. If the discomfort or problem stops, then look closely at the lens.
2. If the lens is in any way damaged, **DO NOT** put the lens back on your eye. Place the lens in the lens case and contact your eye care practitioner.
3. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens

appears undamaged, thoroughly clean, rinse and disinfect the lens, then reinsert it.

4. If the problem continues, immediately remove the lens and promptly **CONSULT A QUALIFIED HEALTHCARE PROFESSIONAL, SUCH AS AN OPHTHAMOLOGIST OR OPTOMETRIST, AUTHORISED BY NATIONAL LAW TO TREAT SUCH SYMPTOMS**. If any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. Seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

PRECAUTIONS:

- Contact lens solutions are intended to be discarded after each use. **DO NOT RE-USE**.
- Check that cap seal is intact before first use. If cap seal is not intact or the packaging is damaged, do not use.
- Keep the bottle tightly closed when not in use.
- Once the bottle is open, discard any remaining solution after 90 days.
- Store solution at room temperature.
- Use before the expiration date marked on the carton and bottle.
- Keep out of reach of children.
- Keep away from sunlight.

LENS AND LENS CASE CARE:

- Rinse lens case and caps with fresh **Eyedia Multi-Purpose Solution** after each use; flip lens case over while air drying to ensure no residual solution remains in the case.
- Replace your lens case at least once every one to three months.
- Always handle the same lens, the right or the left, first in order to avoid mix-ups.
- Do not wear lenses longer than prescribed.

PERFORMANCE CHARACTERISTICS AND CLINICAL BENEFIT(S):

Eyedia Multi-Purpose Solution is a gentle and non-irritating disinfecting solution formulated with pH, osmolarity and tonicity matching the range of healthy human tears. **Eyedia Multi-Purpose Solution** has been shown to be biocompatible in the ocular environment and does not change the physical parameters of soft hydrophilic contact lenses.

The PHMB in **Eyedia Multi-Purpose Solution** serves as the disinfecting agent. An independent research study in 2016 have shown that multipurpose contact lens solutions containing PHMB as a disinfecting agent are effective against germs that can cause keratitis (inflammation of the cornea) and eye infections.¹

¹ Component Analysis of Multipurpose Contact Lens Solutions To Enhance Activity against Pseudomonas aeruginosa and Staphylococcus aureus, Leo Lin, Janie Kim, Hope Chen, Regis Kowalski, and Victor Nizet; July 2016, Antimicrobial Agents and Chemotherapy; Volume 60, Number 7

STORAGE CONDITIONS:

Store lenses between 20°C to 25°C. Shelf life (unopened): 49 months from manufacturing date.

HOW SUPPLIED:

Eyedia Multi-Purpose Solution is supplied in sterile 100 mL, 120 mL, 230 mL and 360mL plastic bottles. The bottles and cartons are marked with lot number and expiration date.

DISPOSAL:

There is no special disposal required for soft contact lens and its blister. The carton packaging, plastic bottles (HDPE) and caps should be placed properly in the waste bin or recycled according to local waste guidance or local regulations.

REPORTING OF ADVERSE REACTION:

All serious adverse experiences and adverse reactions observed in patients wearing this contact lens or experienced with the lens should be reported immediately to the manufacturer and the competent authority of the member state.

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