



Caution

Federal law restricts this device to sale by or on the order of a licensed practitioner

PRODUCT DESCRIPTION

Lenses material is made of 42% Etafilcon A and 58% waters of water content (58 ± 1%). The hydrogel lens material is a random copolymer Lenses are supplied sterile in sealed blister packs containing sterile isotonic phosphate buffered saline.

The Zonedin (Etafilcon A) Contact Lens visibility tint with UV blocker are to be prescribed for single-use disposable daily wear or frequent/planned replacement wear with cleaning, rinsing, disinfection and scheduled replacement as prescribed by the eyecare professional.

ACTIONS:

In its hydrated state, the Zonedin (Etafilcon A) Contact Lens visibility tint with UV blocker when placed on the cornea acts as a refracting medium to focus light rays on the retina.

INDICATIONS (USES):

Zonedin (Etafilcon A) Contact Lens visibility tint with UV blocker is indicated for **daily wear** the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic or hyperopic and may exhibit refractive astigmatism up to 2.00 diopters that does not interfere with visual acuity.

Eye care practitioners may prescribe the lenses for either single-use daily disposable wear or frequent/planned replacement wear with cleaning, rinsing, disinfection and scheduled replacement **as prescribed by the eyecare professional.** When prescribed for frequent/planned replacement wear , The contact lens may be disinfected using chemical (not heat) disinfection system.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE this contact lens when any of the following conditions exist:

- 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 lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Allergy to any ingredient, such as mercury or Thimerosal, in a solution which is to be used to care for the lenses prescribed on a frequent replacement wear schedule
- Any active corneal infection(bacterial, fungal, or viral)
- If eyes become red or irritated

WARNINGS

After a thorough eye examination, including appropriate medical background, patients should be fully apprised by the prescribing practitioner of all the risks with contact lens wear. Patients should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses could result in serious injury to the eye. It is essential that patients follow their eye care practitioner's direction and all labeling instructions for proper use of lenses. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.
- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when daily wear lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact his or her eye care practitioner.
- UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV-absorbing eyewear as directed.

NOTE: Long term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-Blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-Blocking contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye care practitioner for more information.

PRECAUTIONS

Precautions for Eye Care Practitioners:
• Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters,

the eye care practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on eye should be carefully monitored by the prescribing eye care practitioner.
- Fluorescein, a yellow dye, should not be used while the patient is wearing the lenses, because the lenses will become discolored. Whenever fluorescein is used, flush the eyes with sterile saline solution. Wait at least 5 minutes before reinserting the lenses. If it is not possible to flush the eyes, wait a minimum of 1 hour before reinserting the lenses. If replaced too soon, the lenses may absorb residual fluorescein.
- Before leaving the eye care practitioner's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.

Eye Care Professionals should instruct the patient to remove lenses immediately if the eyes become red or irritated. Eye Care Professionals should carefully instruct frequent replacement lens wear patients about the following care regimen and safety precautions:

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
- Never use solutions recommended for conventional hard contact lenses only.
- Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection.
- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can damage the Zonedin (Etafilcon A) Contact Lens visibility tint with UV blocker.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn. Prolonged periods of drying can damage lenses. Follow the lens care directions for Care for a Dried Out (Dehydrated) Lens if lens surface does become dried out.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her eye care practitioner. Do not attempt to remove the lens, except on the instructions of the eye care practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, and wearing instructions in the Patient Information Booklet and those prescribed by the eye care practitioner.
- Never wear lenses beyond the period recommended by the eye care practitioner.
- Never allow anyone else to wear your lenses. They have been prescribed to fit your eyes and to correct your vision to the degree necessary. Sharing lenses greatly increase the chances of eye infections.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eye care practitioner about wearing lenses during water activities and other sports.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Always discard disposable lenses after the recommended wearing schedule prescribed by the eye care practitioner.
- Always contact the eye care practitioner before using any medicine in the eyes.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

ADVERSE REACTIONS

The patient should be informed that the following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when lens was first placed on eye
- Abnormal feeling of something in the eye (foreign body, scratched area)
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

If the patient notices any of the above, he or she should be instructed to:

- **Immediately remove lenses.**
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, do not put the lens back on the eye. Discard the lens and replace it with a new fresh lens. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should discard the lens and replace it with a new fresh lens. After insertion of a new lens, if the problem continues, the patient should **immediately remove the lenses and consult the eye care practitioner.**

When any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. The patient should keep lens off the eye and Seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

WEARING SCHEDULE

The wearing and replacement schedules should be determined by the eye care practitioner. Patients tend to overwear the lenses initially. The eye care practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner, are also extremely important.

The recommended maximum wearing schedule is:

<i>Maximum Wearing Time</i>	
Day	Wear Time (Hours)
1st	4
2nd	6
3rd	8
4th	10
5th	12
6th	14
7 th and above	All waking hours*

* The wearing schedule should be determined by the eye care practitioner. Studies have not been performed to support safety for extended wear (greater than 24 hours) of this lens.

LENS CARE DIRECTIONS

For Zonedin (Etafilcon A) Contact Lens visibility tint with UV blocker: The Eye Care Professional should review with the patient that **no cleaning or disinfection is needed with disposable lenses.** Patients should always dispose of lenses when they are removed and have replacement lenses or spectacles available.

For Zonedin (Etafilcon A) Contact Lens visibility tint with UV blocker prescribed for frequent replacement wear: The Eye Care Professional should review with the patient the lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient.

GENERAL LENS CARE (To first clean and rinse, then disinfect lenses)

Basic Instructions

- Always wash, rinse and dry hands before handling contact lenses.
- Always use fresh, unexpired lens care solutions.
- Use the recommended system of lens care, chemical (not heat), and carefully follow instructions on solution labeling. Different solutions cannot always be used together and not all solutions are safe for use with all lenses. Do not alternate or mix lens care systems unless indicated on solution labeling.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- Lenses should be cleaned, rinsed and disinfected each time they are removed. Cleaning and rinsing are necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs.
- Always remove, clean, rinse and disinfect lenses according to the schedule prescribed by the Eye Care Professional. Enzyme as frequently as recommended by the Eye Care Professional. The use of an enzyme or any cleaning solution does not substitute for disinfection.
- The Eye Care Professional should recommend a care system that is appropriate for the Zonedin (Etafilcon A) Contact Lens visibility tint with UV blocker prescribed on a frequent replacement schedule. Each lens care product contains specific directions for use and important safety information, which should be read carefully and followed.

Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.

- **Clean** one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucus and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.

- After cleaning, disinfect lenses using the system recommended by the manufacturer and/or the Eye Care Professional.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the Package Insert or the Eye Care Professional for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals, as recommended by the lens case manufacturer or your Eye Care Professional.
- Eye Care Professionals may recommend a lubricating/rewetting solution that can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

CHEMICAL (NOT HEAT) DISINFECTION OF LENSES WORN ON A FREQUENT REPLACEMENT SCHEDULE

- **Clean** the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- **After cleaning**, disinfect by carefully following the instructions accompanying the disinfecting solution in the care regimen recommended by the lens manufacturer or the Eye Care Professional.
- When using hydrogen peroxide lens care systems, **lenses must be neutralized before wearing.** Follow the recommendations on the hydrogen peroxide system labeling.
- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- **Do not heat the disinfection solution and lenses.**
- Leave the lenses in the unopened storage case until ready to put on the eyes.

Caution: Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution, which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement on the eye should reduce the potential for irritation.

LENS CASE CLEANING AND MAINTENANCE

Contact lens cases can be a source of bacterial growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer and allowed to air dry. Lens cases should be replaced at regular intervals, as recommended by the lens case manufacturer or your Eye Care Professional.

CARE FOR A DRIED OUT (DEHYDRATED) LENS

If the frequent replacement lens is off the eye and exposed to air from 30 minutes to 1 hour or more, its surface will become dry and gradually become nonwetting. If this should occur, discard the lens and use a new one.

CARE FOR A STICKING (NON-MOVING) LENS

If the lens sticks (stops moving), the patient should be instructed to apply a few drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after a few minutes, the patient should immediately consult the Eye Care Professional.

EMERGENCIES

The patient should be informed that If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: **FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

HOW SUPPLIED:

Zonedin (Etafilcon A) Contact Lens visibility tint with UV blocker are supplied sterile in sealed blister packs containing sterile isotonic phosphate buffered saline. Each container is marked with the manufacturing lot number of the lens, base curve, lens color, diopter power, diameter and expiration date.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing the Zonedin (Etafilcon A) Contact Lens visibility tint with UV blocker or experienced with the lenses should be reported to **Zonedin Vision, LLC.**

Zonedin Vision ,LLC.

Address:5801 N. 10th St., Suite 100 McAllen, TX 78504.

Email: info@zonedinvision.com

Print date: 10/08/19



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- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn. Prolonged periods of drying can damage lenses. Follow the lens care directions for Care for a Dried Out (Dehydrated) Lens if lens surface does become dried out.
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- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, and wearing instructions in the Patient Information Booklet and those prescribed by the eye care practitioner.
- Never wear lenses beyond the period recommended by the eye care practitioner.
- Never allow anyone else to wear your lenses. They have been prescribed to fit your eyes and to correct your vision to the degree necessary. Sharing lenses greatly increase the chances of eye infections.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eye care practitioner about wearing lenses during water activities and other sports.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
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- Do not touch the lens with fingernails.
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- Always contact the eye care practitioner before using any medicine in the eyes.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

ADVERSE REACTIONS

The patient should be informed that the following problems may occur: