

Package Insert

Important: Please read carefully and keep this information for use.

Description:

Single Vision (Hioxifilcon D) Soft (Hydrophilic) Contact Lens for Daily Wear Disposable

Water Content: 55%
Visible Light Transmittance: Over 90%
Oxygen Permeability: 22
Diameter(mm): 14.2
Base Curve(mm): 8.6
Center Thickness (mm): 0.10 at -3.00D
Spherical Power: +6.00~-10.00D

The ZonedIn Soft contact lens is a device in spherical designs intended to be worn directly against the cornea and adjacent limbal and scleral areas of the eye to correct vision conditions. The device is made of various polymer materials the main polymer molecules of which absorb or attract a certain volume (55% daily wear disposable) of water.

Actions:

In their hydrated state, daily wear when placed on the cornea, act as refracting media to focus light rays on the retina.

Indications (Uses): for the correction of eyesight (daily wear disposable) - myopia, hyperopia

Contraindications (Reasons not to use):

- DO NOT USE daily wear when any of the following conditions exist:
- Acute and subacute inflammation or infection of the anterior chamber of the eye
 - Any eye disease (Corneal neovascularization, Corneal erosion, Corneal ulcer, Conjunctivitis, Keratitis), injury, or abnormality that affects the cornea, conjunctiva, or eyelids
 - Insufficiency of lacrimal secretion (dry eyes)
 - Corneal hypoesthesia (reduced corneal sensitivity)
 - 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 lens
 - Any active corneal infection (bacterial, fungal, or viral)
 - If the eyes become red or irritated

Warnings:

- Patients should be advised of the following warnings pertaining to contact lens wear:
- Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that patients follow their eyecare practitioner's direction and all labeling instructions for proper use of lenses and lens care products, including the lens case. 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 these 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 the lenses and promptly contact his or her eyecare practitioner.

Precautions:

- 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 eyecare 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 eyecare practitioner should carefully monitor the continuing ocular health of the patient and lens performance on the eye.
 - Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
 - Aphakic patients should not be fitted with Daily Wear until the determination is made that the eye has healed completely.
 - Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use; and the patient should wait at least 1 hour before replacing the lenses.
 - Before leaving the eyecare 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.
- Eyecare practitioners should carefully instruct 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 approved by your doctor.
 - Never use solutions recommended for conventional hard contact lenses only.
 - Always use fresh unexpired lens care solutions.
 - Always follow directions in the package inserts for the use of contact lens solutions.
 - 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 (stored). Prolonged periods of drying may damage the 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 eyecare practitioner.
 - Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorant, or sprays in the eyes or 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, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for Daily Wear and those prescribed by the eyecare practitioner.
 - Never wear lenses beyond the period recommended by the eyecare practitioner.
 - 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 on hard surfaces.
 - Avoid all harmful or irritating vapors and fumes while wearing lenses.
 - Ask the eyecare 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 contact the eyecare 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.
 - Daily Wear are intended to be disposed of at the end of the indicated period (1 day, 1 week, 2 weeks, or 1 month). Therefore, it is important to always have a pair of replacement lenses available.
- * Precautions pertaining to cleaning and disinfection are not applicable to daily wear disposable lenses.

Adverse Effects:

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

- Eye pain
- Eyes sting, burn, or itch (irritation)
- 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
- Corneal neovascularization, Corneal erosion, Corneal ulcer, Conjunctivitis, Keratitis

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 (for disposable lens). Place the lens in the storage case and contact the eyecare practitioner. 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 one (for disposable) thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, the patient should IMMEDIATELY remove the lenses and consult the eyecare practitioner.
- When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to keep lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

Fitting:

How to put on the lens (A type)



Place the lens on the index finger tip. With the other index finger pull the upper eye lid upward slightly.



Pulling down the bottom eye lid slightly with the middle finger, place the lens on the center of the pupil slightly.



Close your eyes slightly and move your eyes slowly. And the lenses settle down.

How to put on the lens (B type)

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Cleanse the lenses and check the sides (front and back). Please the lenses on the index finger tip like the picture.



Look at the lens in front of you. With the middle finger (same hand), pull down the bottom eyelid slightly.



Looking above the lens, place it on the white of the eye carefully and release the bottom eyelid.



Close your eyes slightly and move your eyes slowly. And the lenses settle down.

How to take off the lens

1. Wash the hands before you take off the lens.
2. Look at a mirror and verify the place of lens.
3. Open the upper eyelid to above with left finger and lower eyelid to below with middle finger of right hand.



a. Open the eye and the pupil of the eye should face the upper direction. With middle finger, take down the lower eyelid to the lower direction and drag the lens down to the sclera.



b. With first and second finger, slightly take the lower part of the lens, so the lens is folded, then the lens will come out naturally. After taking out the lens, you should clean and sterilized the lens immediately, so the edge of lens doesn't stick each other.

surface remains dry, **DO NOT PLACE THE LENS IN THE EYE.** Contact the eye care practitioner.

Care for a Sticking Lens:

If the lens sticks (stops moving), the patient should be instructed to apply 1 to 2 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 5 minutes, the patient should immediately consult the eyecare practitioner.

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 patients should **FLUSH EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVE LENSES PROMPTLY. CONTACT THE EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

How Supplied:

Each lens is supplied sterile in a blister or vial pack containing buffered saline solution. The blister/vial pack is labeled with the Base Curve, Diopter Power, Diameter, Lot Number, and Expiration Date of the product.

Basic Instructions:

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use fresh, unexpired lens care solutions. Never re-use solution.
- Use the recommended system of lens care, chemical (not heat), oxidation (hydrogen peroxide) 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 practitioner. The use of an enzyme or a cleaning solution does not substitute for disinfecting.
- The eye care practitioner should recommend a care system that is appropriate for Daily Wear. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.
- **Note:** Some solutions may have more than one function, which will be indicated on the label. Read the label on the label. Read the label on the solution bottle, and follow instructions.

Lens Case Cleaning and Maintenance:

Contact lens cases can be a source of bacteria 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 the eyecare practitioner.

Care for a Dried Out (Dehydrated) Lens:

If Daily Wear are off the eye and exposed to air for twenty minutes or longer, they will become dry and brittle. To rewet lenses:

- Place the lens in its storage case and soak the lens in recommended rinsing and storage solution for at least one hour or until the lens again feels soft and pliable.
- Clean, rinse and disinfect the re-wetted lens using the lens care system recommended by the eye care practitioner.
- If after soaking, the lens does not become soft or the

Symbol Description

	Used by
	Batch code
	Caution
	Date of Manufacture
	Do Not Reuse (for Disposable lens)
	Manufacturer
	Sterilized using steam or dry heat
DIA	Diameter
B.C	Base Curve
P.	Power (Diopter)

Reporting of Adverse Reactions:

All serious adverse experiences and adverse reactions observed in patients wearing Daily Wear should be reported to:

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