

Patient Instruction/ Wearer's Guide

**clearcolor 1-day (Hioxifilcon A)
DAILY DISPOSABLE COLOR SOFT CONTACT LENS**

***CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE
ORDER OF A LICENSED PRACTITIONER.***



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CONGRATULATIONS

You have just received your new **clearcolor 1-day (Hioxifilcon A) Daily Disposable Color Soft Contact Lens**. This booklet has been prepared to help you care for it. Please read it carefully and follow the instructions so that you receive full satisfaction from your lens.

PRACTITIONER : _____

ADDRESS : _____

TELEPHONE : _____

Lubricant/Rewetting Drops: _____

Rewetting Solution : _____

WEARING AND APPOINTMENT SCHEDULE

Prescribed Wearing Schedule

Day	Wearing Time (Hours)	Day	Wearing Time (Hours)
1	_____	8	_____
2	_____	9	_____
3	_____	10	_____
4	_____	11	_____
5	_____	12	_____
6	_____	13	_____
7	_____	14	_____

APPOINTMENT SCHEDULE

Your appointments are on:

Minimum number of hours lenses to be worn at time of appointment:

Month: _____ **Year:** _____
Time: _____ **Day:** _____

Month: _____ **Year:** _____
Time: _____ **Day:** _____

INTRODUCTION

With your decision to wear soft (hydrophilic) contact lens, you have joined a growing number of people who are discovering new pleasures from this important advance in vision correction.

Your **clearcolor 1-day (Hioxifilcon A) Daily Disposable Color Soft Contact Lens** is made of a stable, inert, highly purified, hydrophilic (water absorbing) polymer with properties different from conventional rigid lens. Fully molded to optical precision in the dry state, your lens holds these qualities in the soft, moist state in which they are suited for your use. Kept moist by the tears in your eyes, the lens is soft and comfort can be immediate. You are cautioned, however, to follow the initial wearing time schedule prescribed by your practitioner and not to overwear the lens simply because they remain comfortable. Your eyecare practitioner will determine your appropriate wearing schedule.

Although soft and pliable, your lens is strong and durable. **clearcolor 1-day (Hioxifilcon A) Daily Disposable Color Soft Contact Lens** is designed as a Daily Disposable and should be worn one day only. As with all precision devices, proper use will assure you the benefits of convenience, comfort, and confidence in your lens.

Read this Wearer's Guide carefully. It contains the information you need to know to wear, handle, and care for your **clearcolor 1-day (Hioxifilcon A) Daily Disposable Color Soft Contact Lens**. If you are in doubt about any instructions, request clarification from your eyecare practitioner.

WEARING RESTFCTIONS and INDICATIONS

The **clearcolor 1-day (Hioxifilcon A) Daily Disposable Color Soft Contact Lens** is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism. The lens is available tinted and may be used to enhance or alter the apparent color of the eye.

The lens is intended to be worn once and then discarded at the end of each wearing period on a daily basis. The patient should be instructed to start the next wearing period with a new lens.

The **clearcolor 1-day (Hioxifilcon A) Daily Disposable Color Soft Contact Lens** described in this booklet should be designed as a Daily Disposable.

The lens is designed for daily wear (less than 24 hours while awake). The maximum wearing time should be determined by the eyecare professional based upon the patient's physiological eye condition because individual responses to contact lenses vary. Patients tend to overwear the lenses initially. The eyecare professional should stress the importance of adhering to the initial maximum wearing schedule. Studies have not been

conducted to show that **clearcolor 1-day (Hioxifilcon A) Daily Disposable Color Soft Contact Lens** is safe to wear during sleep; therefore patients should be advised to remove their lenses while sleeping. Normal daily wear of lenses assumes a minimum of 6 hours non-lens wear per 24 hours period. Optimum individual wearing schedule will vary.

DO NOT WEAR YOUR clearcolor 1-day (Hioxifilcon A) Daily Disposable Color Soft Contact Lens WHILE SLEEPING.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the **clearcolor 1-day (Hioxifilcon A) Daily Disposable Color Soft 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 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.
- Patients unable to follow lens care regimen or unable to obtain assistance to do so.

WARNINGS

- PROBLEMS WITH CONTACT LENS AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE, It is essential that you follow your eyecare practitioner's direction and all labeling instructions for proper use of lens and lens care products, including the lens case. EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; THEREFORE, IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, OR REDNESS OF THE EYE, IMMEDIATELY REMOVE YOUR LENS AND PROMPTLY CONTACT YOUR EYECARE PRACTITIONER.
- Daily wear lenses are not indicated for overnight wear, and you are instructed not to wear the **clearcolor 1-day (Hioxifilcon A) Daily Disposable Color Soft Contact Lens** 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 do.

PRECAUTIONS

- The lens is intended to be worn once and then discarded at the end of each wearing period.
- The patient should be instructed to start the next wearing period with a new lens.
- Emergency lens cleaning and disinfection is not recommended.
- The patient should be reminded to have replacement lenses or back-up spectacles available at all times.
- Always wash and rinse hands before handling lens.
- Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lens.
- It is best to put on lens before putting on makeup. Water-base cosmetics are less likely to damage lens than oil-base.
- Do not touch contact lens with the fingers or hands if the hands are not free of foreign materials, as microscope scratches of the lens may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfection, storing and wearing instructions in the patient instructions for the **clearcolor 1-day (HioxifilconA) Daily Disposable Color Soft Contact Lens** and those prescribed by the eyecare practitioner.
- Never wear lens beyond the period recommended by the eyecare practitioner.
- If aerosol products such as hair spray are used while wearing lens, exercise caution and keep eyes closed until the spray has settled.
- Always handle lens carefully and avoid dropping them.
- Avoid all harmful or irritating vapors and h e s while wearing lens.
- Ask the eyecare practitioner about wearing lens during sporting activities.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lens 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 or medications 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 lens.
- 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 following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when lens was first placed on eye.

- Feeling that something is in the eye such as a foreign body or 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 LENS.

- If discomfort or problems stops, then look closely at the lens. If the lens is damaged, **DO NOT PUT THE LENS BACK ON YOUR EYE.** Discard the lens and replace with a fresh lens. After reinsertion, if the problem continues, you should **IMMEDIATELY REMOVE THE LENS AND CONSULT YOUR EYECARE PRACTITIONER.**

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. **KEEP LENS OFF THE EYE AND SEEK IMMEDIATE PROFESSIONAL IDENTIFICATION** of the problem and prompt treatment to avoid serious eye damage.

PERSONAL CLEANLINESS and LENS HANDLING

Before Handling Your Lens:

Cleanliness is an important aspect of contact lens care.

- Before handling your lens, always wash and rinse your hands thoroughly and dry them with a lint-free towel.
- Do not use soaps, lotions, cold creams, or perfumes which leave a residue on your hands.
- Avoid using medications, creams, deodorants, make-up, after shave lotions, or similar items prior to touching your lens.
- When hair spray is used, the eye must be kept closed until the spray has settled.
- Take care in handling your lens. Always avoid touching your lens with your fingernails or other sharp objects.
- **NEVER WORK DIRECTLY OVER A SINK WITH THE DRAIN OPEN, AS THE LENS MAY BE LOST.**

Handling and Placing the Lens on the Eye:

- 1) To avoid the possibility of lens mix-ups, always start with the same lens first.
- 2) Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear and free of any nicks or tears.
- 3) Place the lens on the tip of the index finger of your dominant hand.

- 4) While positioned on your index finger, check to ensure the lens has not turned inside out. To check this, look at the profile of the lens against a light background. If the edge profile appears convex and bowl-shaped, then it is correct. If the lens is inverted, it will flare out at the edge. If the lens is inverted, simply reverse it by using light fingertip pressure. Be sure to avoid damaging the lens with your fingernails.
- 5) Look straight ahead and raise the upper lid with your other index finger.
- 6) Then look down, keep both eyes open and place the lens on the upper white part of the eye.
- 7) Slowly release upper lid, and gently close your eye.
- 8) The lens should center automatically, or it can be moved on center by gentle fingertip pressure through the lids.
- 9) Repeat the above procedure for the second lens.
- 10) If the lens appears to be stuck on your eye, apply a few drops of a recommended lubricating or rewetting solution to the eye and blink a few times. If the lens does not move freely on your eye, contact your eyecare practitioner for further instructions.

There is no single "right way" of putting on lens. If you find this method of lens placement difficult, your eyecare practitioner will suggest another method or provide additional information.

NOTE : If after replacement of the lens, your vision is blurred, check for the following:

- The lens is not centered on the eye (see "Centering the lens" next in this booklet.
- If the lens is centered, remove the lens (see "Removing the lens" section) and check the following:
 - a. Cosmetic or oils on the lens. Discard lens and place a new lens on the eye again.
 - b. The lens is on the wrong eye.
 - c. The lens is inside-out (it would be also not be as comfortable as normal)

If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your eyecare practitioner.

Centering the lens:

Very rarely a lens that is on the cornea will be displaced onto the white part of the eye during lens wear. This can also occur during placement and removal of the lenses if the correct techniques are not performed properly. To center a lens, follow the procedure outlined below.

Using your index finger, gently apply pressure to the lens and slide it back into the cornea. If the lens gets under the upper lid, gently massage the upper lid while looking down and move the lens toward the cornea.

Removing the Lens:

Preparation:

- 1) Wash and rinse your hands thoroughly.
- 2) Dry hands with a lint-free towel.
- 3) Check that the lens is centered on the cornea before attempting to remove the lens. Check your vision by covering one eye. If vision is blurry, the lens is off-centered. Re-center the lens before attempting to remove it.

Removal:

- 1) To avoid the possibility of lens mix-ups, always begin with the same lens.
- 2) Look up and keep both eyes open.
- 3) Using the middle finger of your dominant hand, gently pull down the lower lid of the first eye. Using the tip of your index finger of the same hand, touch the lens and slide it onto the white of the eye.
- 4) Gently "pinch" the lens between the index finger and the thumb and remove.
- 5) Repeat the procedure for the second eye.
- 6) If the lens cannot be easily moved, contact your eyecare practitioner for further instruction.
- 7) Upon removal, discard the lens.

IMPORTANT:

Always avoid touching your lens with your fingernails. Use only your fingertips.

If you find this method difficult, your eyecare practitioner will suggest another method or provide additional instruction.

CARING FOR YOUR LENS**Basic Instructions:**

The **clearcolor 1-day (Hioxifilcon A) Daily Disposable Color Soft Contact Lens** described in this booklet are designed as a Daily Disposable lens.

The lens is intended to be worn once and then discarded at the end of each wearing period. You are instructed to start the next wearing period with a new lens. You are also instructed to always have a pair of lenses with you at all times.

The lens is designed for daily wear (less than 24 hours while awake). The maximum wearing time should be determined by the eyecare professional based upon the patient's physiological eye condition because individual responses to contact lenses vary. Patients tend to overwear the lenses initially. The eyecare professional should stress the importance of adhering to the initial maximum wearing schedule. Studies have not been conducted to show that **clearcolor 1-day (Hioxifilcon A) Daily Disposable Color Soft Contact Lens** is safe to wear during sleep; therefore patients should be advised to remove their lenses while sleeping. Normal daily wear of lenses assumes a minimum of 6 hours non-lens wear per 24 hour period. Optimum individual wearing schedule will vary.

You should adhere to a recommended daily disposable care regimen. Failure to follow the regimen may result in development of serious ocular complications as discussed in the warning section above.

If you require only vision correction, but will not or cannot adhere to a recommended care regimen for your lens, or are unable to place and remove your lens or have someone available to place and remove them, you should not attempt to get and wear contact lens.

When you first get your lens, be sure you have to put the lens on and remove them while you are in your eyecare practitioner's office.

Your eyecare practitioner should instruct you about appropriate and adequate procedures and products for your use, and provide you with a copy of the Wearer's Guide for the **clearcolor 1-day (Hioxifilcon A) Daily Disposable Color Soft Contact Lens**.

For safe contact lens wear, you should know and always practice your lens care routine:

- Always wash, rinse, and dry hands before handling contact lens.
- Do not use saliva for lubricating or rewetting lens. Do not put lens in the mouth.

Care for a Sticking (non-moving) Lens:

If the lens sticks (cannot be removed), you should apply 3 to 4 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 15 minutes, you should **IMMEDIATELY** consult your eyecare practitioner.

EMERGENCIES

If any chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, you should:

FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT YOUR EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

WHEN TO CALL YOUR PRACTITIONER?

Certain symptoms may be early indicators of potentially serious problems. A careful examination of your lens, and professional examination of your eyes, may be required. Remove the lens following the instructions outlined in this guide, and you're your eyecare practitioner if:

- 1) Your eye becomes red and feels irritated or "gritty".
- 2) You notice a change in your vision or see rainbows or halos around objects.
- 3) You experience discomfort and/or sensitivity to lights.

A good general policy is:

"IF IN DOUBT ... TAKE THE LENS OUT" and contact your eyecare practitioner.

Learn and Use Proper lens Care Habits:

- 1) Follow Instructions.
- 2) Handle Lens Properly.
- 3) Learn How to Put On and Take Off Your Lens.
- 4) Always use a fresh lens at the start of the wearing period.

INSTRUCTIONS FOR MONOVISION WEARER

- You should be aware that as with any type of lens correction, there are advantages and compromises to monovision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to it. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations, which are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with monovision correction if you pass you state driver's license requirements with monovision correction.
- Some monovision patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your eyecare practitioner having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.
- If you require very sharp near vision during prolonged close work, you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required.
- Some monovision patients require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this with your eyecare practitioner.
- It is important that you follow your eyecare practitioner's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.

- The decision to be fit with monovision correction is most appropriately left to the eyecare practitioner in conjunction with you, after carefully considering and discussing your needs.

WEARING SCHEDULE

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY YOUR EYECARE PRACTITIONER.

The **clearcolor 1-day (Hioxifilcon A) Daily Disposable Color Soft Contact Lens** is indicated for daily wear. The maximum suggested wearing time for this lens is:

<u>DAY</u>	<u>HOURS</u>
1	6
2	8
3	10
4	12
5	14
6	All Waking hours*

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE “clearcolor 1-day (Hioxifilcon A) Daily Disposable Color Soft Contact Lens” IS SAFE TO WEAR DURING SLEEP.

IMPORTANT

In the event that you experience any difficulty wearing your lens or you do not understand the instructions given you, **DO NOT WAIT** for your next appointment. **TELEPHONE YOUR EYECARE PRACTITIONER IMMEDIATELY.**

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