WARNINGS
practitioners may prescribe the lens for daily wear and/or frequent replacement. When prescribed for a Frequent Astigmatism up to 4.00 diopters. The lenses may be disinfected using a heat, or chemical disinfection system. Eyecare lenses, or bifocal (two power) lenses. The lens material (hioxifilcon A) is a copolymer of 2-hydroxyethyl methacrylate exist:

CONTRAINDICATIONS (REASONS NOT TO USE)

Hydrophilic Contact Lens

INDICATIONS (USES)
The PERFORMANCE® (hioxifilcon A) Hydrophilic Contact Lenses are indicated for daily wear for the correction of refractive errors (myopia and hyperopia) that may include presbyopia with non-disosed eyes that may exhibit astigmatism up to 4.00 diopters. The lenses may be disinfected using a heat, or chemical disinfection system. Eyecare practitioners may prescribe the lens for daily wear and/or frequent replacement. When prescribed for a Frequent Replacement Program, the lenses may be disinfected using heat, or chemical disinfection systems.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE THE PERFORMANCE® (hioxifilcon A) Hydrophilic Contact Lenses when any of the following conditions exist:

WARNINGS

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that patients follow their eye care professional’s directions and all labeling instructions for proper use of their 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 their lenses while sleeping. Clinical study results have shown that the risk of serious adverse reactions including ulcerative keratitis is nine times greater for daily wear users who wear their lenses overnight (outside the approved indication) compared to those who do not wear them overnight. Studies have also shown that contact lens wearers who smoke have a higher incidence of adverse reactions (estimated 3 to 6 times greater risk of suffering ulcerative keratitis) than among those who are non-smokers. 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. It is recommended that contact lens wearers see their eye care professional regularly as directed.

PRECAUTIONS

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 the eye should be carefully monitored by the prescribing eyecare practitioner.

ADVERSE EFFECTS

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

REPORTING ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing the PERFORMANCE® (hioxifilcon A) Hydrophilic Contact Lenses should be reported by licensed eye care practitioners to:

OPTIK K&R Inc.
425 Midwest Road Toronto, Ontario M3J 3A4
Canada
Tel: (800) 465-0048 or (416) 915-1500
Fax: (416) 234-6529 or (416) 915-1501
Email: info@kandr.com

SELECTION OF PATIENTS

PERFORMANCE® (hioxifilcon A) Hydrophilic Contact Lenses is intended for the daily wear patient who may require the correction of visual acuity for myopia, hyperopia or astigmatism up to 11.00 diopters. PERFORMANCE® (hioxifilcon A) Hydrophilic Contact Lenses are suitable for patients who have never worn contact lenses, for current PMMA wearers, for patients wanting to upgrade their current soft contact lenses, as well as for some patients who are unsatisfactory with rigid gas permeable lenses.

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 unused lens care solution. Always follow directions in the package inserts for the use of contact lens solutions. Steer unreserved solutions, when used, should be discarded after the date 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 directions for CARE FOR A DRIED OUT (DIOHYDRATED) 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 new, cosmetics, lotions, creams, deodorant, or sprays in the eyes or on the lenses. It is best to put on lenses putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based 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 the PERFORMANCE® (hioxifilcon A) Hydrophilic Contact Lenses and those prescribed by the eyecare practitioner.

• Never wear lenses beyond the period recommended by the eyewear 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. Place the lens into the hand.

• Do not touch the lens with fingernails.

• Always contact eyecare practitioner before using any medication 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 recommended follow-up schedule.

• PERFORMANCE® (hioxifilcon A) Hydrophilic Contact Lenses when prescribed in a Frequent Replacement Program are intended to be dispensed at the end of the prescribed period (1 week, 2 weeks, 1 month, etc.). Therefore, it is important to always have available a pair of replacement lenses.

ADVERSE EFFECTS

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

• Eye pain

• Eyes sting, burn, or itching (irritation)

• 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 lens(es).

• 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. 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 thoroughly clean, rinse, and disinfect the lenses; then reimst them. After rinsention, IF THE PROBLEM CONTINUES, THE PATIENT SHOULD IMMEDIATELY REMOVE THE LENSES AND CONTACT THEIR EYE CARE PROFESSIONAL AT ONCE.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularisation, or rift 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.
LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE

Hydrophilic Contact Lenses may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement on the eye should be performed.

Chemical (Not Heat) Disinfection

Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.

After cleaning, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by the eye care practitioner.

DO NOT USE hydrogen peroxide lens care system. Peroxides may cause the lens to yellow.

Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfecting solution labeling.

Do not heat the disinfection solution and lenses.

Leave the lenses in the unopened storage unit until ready to put on the eyes.

CAUTIONS: Lenses that are chemically disinfecting 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 DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE

The eye care practitioner may recommend enzyme cleaning. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for well-being of the patient’s lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

LENS CASE CLEANING AND MAINTENANCE

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed and refilled periodically. Lenses stored longer than 12 hours may require cleaning, rinsing and disinfection again before use. The patient should consult the lens care regimen recommended for the patient’s lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

LENS CASE CLEANING AND MAINTENANCE

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed and refilled periodically.

LENS CARE DIRECTIONS

Eye care practitioners should review with the patient 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 check the expiry date on the lens care solutions.
- Use the recommended system of lens care, either heat or chemical (not heat) and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe to use with all lenses. Do not alternate or mix lens care system unless instructed 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 mucous and film from the lens surface. Disinfecting is necessary to destroy harmful germs.
- Always remove, clean, rinse, and disinfect lenses daily. Enzyme lenses according to a schedule prescribed by the eye care practitioner. The use of an enzyme in any cleaning solution does not substitute for disinfection.
- The eye care practitioner should recommend a care system that is appropriate for the PERFORMANCE® (hioxifilcon A) Hydrophilic Contact Lenses. 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 solution bottle, and follow instructions.
- Clean one lens first (always the same lens first avoid mix-ups), rinse the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucous, 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 eye care practitioner.
- To store lenses, disinfect and leave them in the lens storage case until ready to wear. Lenses stored longer than 12 hours may require cleaning, rinsing and disinfecting again before use. The patient should consult the package insert or the eye care practitioner for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with rinsing solution; then allow the lens case to air dry. When the case is used again, refill it with fresh storage solution. Replace lens case at regular intervals.
- Eye care practitioners may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

Heat or Ultraviolet Disinfection (no chemical)

After cleaning and thoroughly rinsing contact lenses with recommended solutions, prepare the empty lens storage case. To keep the lenses wet during disinfection, use the solution that is recommended by the lens manufacturer and/or the eye care practitioner.

Wet the lens chambers (sections) with fresh saline solution.

Put each lens into its correct chamber.

Fill the chambers of the case to the level with fresh saline solution. Completely cover the lenses.

Tightly close the top on each chamber of the lens storage case.

Put the lens storage case into the disinfection unit and follow the disinfection unit manufacturer’s directions for operating the unit (turning the unit on, assuring that it works, and leaving it on for a sufficient time to disinfect the lenses). In the lenses, no rinsing is necessary unless the eye care practitioner recommends rinsing.

Chemical (Not Heat) Disinfection

Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.

After cleaning, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by the eye care practitioner.

DO NOT USE hydrogen peroxide lens care system. Peroxides may cause the lens to yellow.

Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfecting 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.

CAUTIONS: Lenses that are chemically disinfecting 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 DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE

The eye care practitioner may recommend enzyme cleaning. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for well-being of the patient’s lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

LENS CASE CLEANING AND MAINTENANCE

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed and refilled periodically, and allowed to air dry. Lens cases should be replaced at regular intervals.

Hydrophilic Contact Lens

Specific instructions on the lens care regimen recommended for the patient:

General Lens Care

Chemical (Not Heat) Disinfection

Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.

After cleaning, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by the eye care practitioner.

DO NOT USE hydrogen peroxide lens care system. Peroxides may cause the lens to yellow.

Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfecting 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.