

PATIENT INSTRUCTION BOOKLET FOR THE

**SynergEyes® KC and ClearKone Hybrid Contact Lenses for Daily Wear
(paflucocon D – hem-iberfilcon A): Contact Lenses For Keratoconus**

**CAUTION: FEDERAL LAW RESTRICTS THESE DEVICES TO SALE BY OR
ON THE ORDER OF A LICENSED PRACTITIONER**

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INTRODUCTION

SynergEyes® KC and *ClearKone*® (paflucocon D hem-iberfilcon A) Hybrid Contact Lenses provide refractive error correction for keratoconus when worn for daily wear. The lenses are manufactured from paflucocon D with a poly-hema hydrogel skirt (hem-iberfilcon). The lens center provides the optics of rigid gas permeable lenses while the hydrogel skirt provides the stability and performance of hydrogel lenses

WEARING RESTRICTIONS AND INDICATIONS

SynergEyes KC and ClearKone (paflucocon D hem-iberfilcon A) Hybrid Contact Lenses for Keratoconus are indicated for the correction of eyes with refractive errors that include hyperopia and myopia that manifest irregular astigmatism, in aphakic and not aphakic, and otherwise non-diseased eyes. The lenses are indicated for the correction of up to +20.00 and -20.00 D in eyes with irregular astigmatism up to 6.00 D. The lenses may be prescribed for daily wear with removal for cleaning and disinfection (chemical, not heat) prior to reinsertion, as recommended by the eyecare professional.

DO NOT WEAR YOUR SYNERGEYES® KC OR CLEARKONE HYBRID CONTACT LENSES FOR DAILY WEAR WHILE SLEEPING.

CONTRAINDICATIONS (REASONS NOT TO USE)

- Acute and sub-acute inflammations or infection of the anterior chamber of the eye.
- Any eye disease-excluding keratoconus, injury, or abnormality that affects the cornea, conjunctiva or eyelids.
- Severe insufficiency of tears (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 that is to be used to care for contact lenses
- Any active corneal infection (bacterial, fungal or viral), or
- If eyes become red or irritated

WARNINGS

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE.

It is essential that you follow the directions of your eyecare practitioner (professional) and all labeling instructions for proper use of contact lenses and lens care products, including the lens case. You should read and follow these instructions for use and warnings pertaining to contact lens wear:

SOAKING AND STORING LENSES INSTRUCTION FOR USE:

Use only fresh multi-purpose (contact lens disinfecting) solution each time you soak (store) your lenses.

WARNING:

DO NOT reuse or “top off” old solution left in your lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness.

“Topping-Off” is the addition of fresh solution to solution that has been sitting the case.

a. Rub and Rinse Time - Instruction for Use:

- Rub and rinse your lenses according to the recommended lens rubbing and rinsing times in the labeling of your multi-purpose solution to adequately disinfect your lenses.

SOAKING AND STORING LENSES INSTRUCTION FOR USE (continued):

WARNING:

- Rub and rinse your lenses for the recommended amount of time to help prevent serious eye infections.
- Never use water, saline solution, or rewetting drops to disinfect your lenses. These solutions will not disinfect your lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.

b. Lens Case Care - Instruction for Use:

- Empty and clean your contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/contact lens cleaner. Never use water. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without any additional cleaning methods. If air drying, be sure that no residual solution remains in the case before allowing it to air dry.
- Replace your lens case according to the directions given by the eyecare professional or the labeling that came with the case. Clean, rinse and air-dry your lens case each time you remove your lenses. In order to permit excess solution to drain, you can flip over your lens case while air drying. Replace your lens case frequently, depending upon your hygiene habits.
- Contact lens cases can be a source of bacterial growth.

WARNING:

- DO NOT store lenses or rinse the lens case with water or any non-sterile solution. Use only fresh multi-purpose solution so you do not contaminate your lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

c. Water Activity - Instruction for Use:

- DO NOT expose your contact lenses to water while you are wearing them.

WARNING:

- Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If your lenses have been submersed in water when swimming in pools, lakes or oceans, you should discard them and replace them with a new pair. Ask your eyecare practitioner for recommendations about wearing your lenses during any activity involving water.

d. Discard Date on Multipurpose Solution Bottle - Instruction for Use:

- Discard any remaining solution after the recommended time period indicated on the bottle of multipurpose solution used for disinfecting and soaking your contact lenses.
- The Discard Date refers to the time you can safely use the contact lens care product after the bottle has been opened. It is not the same as the expiration date, which is the last date that the product is still effective before it is opened.

WARNING:

Using your multi-purpose solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.

- To avoid contamination, DO NOT touch the tip of the container to any surface. Replace cap after using.
- To avoid contaminating your solution, DO NOT transfer to other bottles or containers.

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; IF YOU EXPERIENCE:

- **Eye Discomfort**
- **Excessive Tearing**
- **Eye Redness**
- **Vision Changes**
- **Loss of Vision**
- **Or Other Eye Problems**

IMMEDIATELY REMOVE YOUR LENSES, AND PROMPTLY CONTACT YOUR EYECARE PRACTITIONER.

ADDITIONAL WARNINGS:

Please read 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 you follow your eyecare practitioner's directions and all labeling instructions for proper use of your 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 you should not 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 you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, you should immediately remove the lens and promptly contact your eyecare 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-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eyecare practitioner for more information.

PRECAUTIONS

- Before leaving your eyecare practitioner's office, you should be able to promptly remove lenses or should have someone else available who can remove the lenses for you.
- You should remove the lenses immediately if your eye becomes red or irritated.
- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only the solutions identified in the section titled "LENS CARE DIRECTIONS".
- Do not heat the wetting/soaking solution and lenses. Keep away from extreme heat.
- 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 lens care system can warp the center of the SynergEyes KC and ClearKone Hybrid Contact Lenses.
- 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 drying may damage the silicone hydrogel lens skirt. Follow the lens care directions on *Care for a Dried Out Lens* if the lens skirt becomes dried out.

PRECAUTIONS (continued)

- 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 nonmovement of the lens continues, you should immediately consult your eyecare practitioner.
- Always wash and rinse your 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-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch your contact lenses with fingers or hands if your 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 this booklet for the SynergEyes KC and ClearKone Hybrid contact lenses and those prescribed by your eyecare practitioner.
- Never wear lenses beyond the time recommended by your eyecare practitioner.
- If aerosol products such as hairspray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses carefully and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask your eyecare practitioner about wearing lenses during sporting activities.
- Inform your 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 your hand.
- Do not touch the lens with your fingernails.
- Always contact your eyecare practitioner before using any medicine in the eyes.
- Always inform your employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that you not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. You should follow the visit schedule for follow-up visits.

ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO)

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 of something in the eye such as a foreign body or 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 you notice any of the above, you should: **IMMEDIATELY REMOVE YOUR 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 your eye. Place the lens in the storage case and contact your eyecare practitioner. If the lens has dirt, an eyelash, or other foreign objects on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse and disinfect the lens; then reinsert it.
- After reinsertion, if the problem continues, you should **IMMEDIATELY** remove the contact lenses 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 the lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

PERSONAL CLEANLINESS FOR LENS HANDLING:

1. Preparing the Lens for Wearing

For continued safe and comfortable wearing of your lenses, it is important that you first clean and rinse, then disinfect your lenses after removal, using the care regimen recommended by your eyecare practitioner. If you use a hydrogen peroxide solution, be sure to allow it be neutralized as described in the instructions for the product. Cleaning and rinsing are necessary to remove mucus, secretions, films, or deposits which may have accumulated during wearing. The ideal time to clean your lenses is immediately after removing them. Disinfecting is necessary to destroy harmful germs.

You should adhere to a recommended care regimen. Failure to follow the regime may result in development of serious ocular complications as discussed in the Warnings section of this booklet.

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

When you first get your lenses, be sure you have put them on and removed them in your eyecare practitioner's office. At that time, you will be provided with a recommended cleaning and disinfection regimen and instructions for lens care, handling, cleaning and disinfection. Your eyecare practitioner should instruct you about appropriate and adequate procedures and products for your use, and provide you with a copy of the Patient Instructions for the SynergEyes KC and ClearKone Hybrid Contact Lenses. It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substance when you handle your lenses. The procedures are:

- Always wash your hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching your lenses.
- Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.
- To avoid damaging your lenses, handle them with your fingertips, and be careful to avoid contact with your fingernails. It is helpful to keep your fingernails short and smooth.
- Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.

2. Handling the Lenses:

- Develop the habit of always working with the same lens first to avoid mix-ups.
- Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks and tears.

3. Placing the Lens on Your Eye:

Work over a table, upon which is placed a clean towel. Do not place lenses on your eye while working over a sink. For the right eye:

- Place a mirror flat on the countertop where you will be working with your lenses
- Place the contact lens between the index and middle fingers of your right hand.
- Place 2-3 drops of multipurpose solution in the bowl of the lens before insertion
- Place the second finger of your left hand on the middle of your upper lid and press upward firmly.
- Place the ring finger of the right hand on your lower lid and press downward firmly.
- Look into the mirror as though looking through the contact lens. You will later learn to do this without a mirror.

PERSONAL CLEANLINESS FOR LENS HANDLING (continued):

- Slowly move your hand to advance the forefinger with the contact lens towards the cornea until the lens touches your cornea. Pause and then release the lids.
- After release of the lids and close your eye softly for a few seconds.
- Repeat for your left eye.

There are other methods of lens placement. If the above method is difficult for you, your eyecare practitioner will provide you with an alternate method.

Note: If after placement of the lens, your vision is blurred, check for the following:

- The lens is not centered on your eye (see "Centering the Lens", next section in this booklet).
- Air bubbles may be trapped under the rigid center of the lens. Remove the lens, fill with multipurpose solution and reinsert.
- If the lens is centered, remove the lens (see "Removing the Lens" section) and check for the following:
 - a. Cosmetics or oils on the lens. Clean, rinse, disinfect, and place on the eye again.
 - b. The lens is on the wrong eye.

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

4. Centering the Lens:

Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye (sclera) during lens wear. This can also occur during application and removal of the lenses if the correct techniques are not performed properly.

To center a lens follow this procedure. First locate the lens by pulling away the lids. After the lens is found, gently press on the lid over the lens while looking away from the direction of the lens. Next look back towards the lens.

5. Removing the Lens:

Always remove the **RIGHT** lens first.

- Wash, rinse, and dry your hands thoroughly.
- Work over a table with a clean towel. Do not remove lenses over a sink. Place the second finger of the left hand on the middle of your upper lid and press upward firmly. Look upward. Take the thumb and forefinger of your right hand and gently pinch the soft skirt at the bottom of the lens.
- Do not use the fingernails, rather use the pads of your thumb and finger-tip as you gently pinch the skirt
- As air flows under the lens it will normally stay within your thumb and forefinger. Gently draw the lens downward and outward. Release your left hand and place the lens in the palm of your left hand for cleaning and rinsing prior to storage.
- Remove the other lens by following the same procedure.

Follow the required lens care procedures described under the heading **LENS CARE DIRECTIONS**.

Note: If this method of removing your lens is difficult for you, your eyecare practitioner will provide you with an alternate method.

LENS CARE DIRECTIONS

General Lens Care (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 systems of lens care listed in the box below, which are chemical (not heat) systems 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.**
- To avoid contamination, do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your 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 your lenses according to the schedule prescribed by your eyecare practitioner. The use of any cleaning solution does not substitute for disinfection.
- Ensure that tamper proof seal is intact prior to initial use. Do not use if tamper proof seal is broken or missing.
- Lenses should never be worn while swimming.
- Do not store the lens for prolonged periods at temperatures exceeding 30 deg. C.

Soft contact lens care products are recommended for use with SynergEyes KC and ClearKone Hybrid Contact Lenses.

NOTE: When using hydrogen peroxide lens care systems, **ONLY use the lens case provided with the hydrogen peroxide care system. This case is specially designed to neutralize the solution.** Failure to use the specialized case will result in severe stinging, burning, and injury to the eye. Follow the recommendations on the hydrogen peroxide system labeling exclusively and should be instructed that following disinfection with a peroxide system, the lenses should be rinsed with sterile saline.

NOTE: SynergEyes® KC and ClearKone® (paflucocon D hem-iberfilcon A) Hybrid Contact Lenses cannot be cleaned and disinfected using the following contact lens solutions: OPTIFREE® PUREMOIST® Solution, Revitalens Ocutec® Multipurpose Disinfecting Solution, or Biotrue® Multipurpose Solution.

DETAILED LENS CARE DIRECTIONS (cleaning and maintenance)

1. Clean

While the recommended care products may be approved for a “No Rub” regimen, it is recommended that moderate daily cleaning be conducted with your SynergEyes KC and ClearKone Hybrid Contact Lenses. Clean one lens first (always start with the same lens first to avoid mix-ups). Place the lens, front side down, in the palm of the hand and apply several drops of the multipurpose solution. Using the index finger of the other hand, apply slight pressure in a swirling motion for the time recommended by the multipurpose solution manufacturer. **Note: Do not clean the lens by rubbing it between your thumb and index fingers, as this may cause lens warpage.**

2. Rinse

Rinse the lens thoroughly with the multipurpose solution to remove mucus and film from the lens surface. Place that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.

3. Disinfect

After cleaning and rinsing the lenses disinfect them by using the multipurpose solution. Follow the instructions provided with the multipurpose solution labeling. **Note: SynergEyes KC and ClearKone Hybrid Contact Lenses cannot be heat (thermally) disinfected.**

DETAILED LENS CARE DIRECTIONS (cleaning and maintenance) (continued)

4. Storage

To store lenses, disinfect and leave them in the closed case until ready to wear. Always keep your lenses completely immersed in the multipurpose solution when the lenses are not being worn. If you discontinue wearing your lenses, but plan to begin wearing them again after a few weeks, ask your eyecare practitioner for a recommendation on how to store your lenses.

5. Care of Your Lens Case

Contact lens cases can be a source of bacteria growth. After removing your lenses from the lens case, empty and rinse the lens storage case with solution(s) recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with fresh disinfecting solution. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or your eyecare practitioner.

6. Lubricating/Rewetting Solutions

Your eyecare practitioner will recommend lubricating/rewetting drops for your use. Lubricating/Rewetting drops can be used while you are wearing them to make them more comfortable.

7. Lens Deposits and Use of Enzymatic Cleaning Procedure

Enzyme cleaning may be recommended by your eyecare practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well-being of your lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation. **Enzyme cleaning does not replace routine use of a cleaning and disinfecting solution.**

8. Care for a Sticking (nonmoving) Lens

If the lens sticks (stops moving) or cannot be removed, you should apply 5 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. To initiate movement gently push the lens upward with your index finger on the margin of the lower lid. If non-movement of the lens continues after 30 minutes, you should IMMEDIATELY consult your eyecare practitioner.

9. Care for a Dehydrated Lens

The soft silicone portion of the SynergEyes KC and ClearKone Hybrid Contact Lenses may become dried out if left exposed to air while the lenses are off the eye. Re-hydrate the lens by carefully placing the lens into the storage case and covering it with the multipurpose solution. The lenses should be soaked for a minimum of five minutes or until it returns to a soft state prior to handling. Properly clean, rinse and disinfect the lenses prior to reinsertion. If after soaking, the lens does not become soft or if the surface remains dry, **DO NOT USE THE LENS UNLESS IT HAS BEEN EXAMINED BY YOUR EYECARE PRACTITIONER.**

EMERGENCIES

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes, you should: **FLUSH EYES IMMEDIATELY WITH TAP WATER, THEN REMOVE LENSES PROMPTLY, IF POSSIBLE, AND IMMEDIATELY CONTACT YOUR EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

RECOMMENDED INITIAL WEARING SCHEDULE

Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. You should limit the wearing schedule to the level recommended by your eyecare practitioner regardless of how comfortable the lenses feel.

| | |
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| Day 1 | Wear not to exceed 6 hours total |
| Day 2 | 6 hours |
| Day 3- Day 5 | 8 hours |
| Day 6 | Wear as eyecare practitioner allows during waking hours |

A well fit lens provides for centration and minimal movement. The effects of lid interaction on blinking and gravity may result in lens decentration during open eye wear.

You should remember; “when in doubt, take it out.” It is important that a new wearer not over wear the lens or endure a lens that has an obvious foreign body sensation. In the event of foreign body sensation (feeling of something in your eye), you should remove the lens, clean and rinse it, and replace the lens. If the sensation continues, the lens should not be worn.

You should report for follow-up evaluation at the prescribed follow up schedule. The visit is best scheduled after several hours of wear and you should report with the lens in place. This visit provides an excellent opportunity to evaluate lens fit, comfort, and vision.

Upon the absence of clinical signs and complications, you may be instructed to continue daily wear of the lens until the next scheduled follow-up visit. An alternate initial daily wear schedule may be offered at your practitioner’s discretion.

PATIENT/EYECARE PRACTITIONER INFORMATION

IMPORTANT: In the event that you experience difficulty wearing your lenses or do not understand the instructions given to you, DO NOT WAIT for your next appointment. Talk to your eyecare professional immediately.

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