SynergEyes® KC and ClearKone® (paflufocon D – hem-iberfilcon A) HYBRID CONTACT LENSES FOR
Excessive Tearing
Vision Changes
Eye Redness

ClearKone Hybrid Contact Lenses for keratoconus are indicated for use in the correction of eyes
daily wear.

LICENSED PRACTITIONER

Severe insufficiency of tears (dry eyes)
Corneal hypoesthesia (reduced corneal sensitivity).
Any active corneal infection (bacterial, fungal or viral).
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.

DESCRIPTION

ClearKone Hybrid Contact Lenses are manufactured from rigid gas permeable material
(47x29) and the SynergEyes poly-hema material (shamself). (A): The lenses are designed to have at least
2 zones on the anterior and posterior surfaces:

Zone 1: RGP material or spherical zone
Zone 2: Poly-HEMA material

The peripheral material is a poly-hema hydrophilic copolymer. The lenses are available as bates cat contact lenses with a blue tint in the rigid central material. The blue material contains DMC Green No. 6. The poly-hema skin is clear.

Detailed Description of Keratome Contact Lens

Severe keratoconus. Keratoconus cases with a keratometer reading that is more than 300 degrees or the maximum keratometric power that is above 4.0D. Severe keratoconus requires a lens that is more than 50% thicker than the base curve to provide adequate corneal support and to support the lens over a large area of the cornea.

ClearKone and SynergEyes KC contact lenses are indicated for use in 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

INTRODUCTION

The intermediate spherical zone
The peripheral portion of the steepest meridian and some bearing may appear in the paracentral region of the flattest

WARNINGS: PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that patients follow the directions of the eye care practitioner and use the correct lenses and lens care products, including the lens case. Patients should be advised of the following instructions for use and warnings pertaining to contact lens care:

- Rub and Rinse Time
- Fixation for Use:
- Use all recommended lens care products as directed.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on
- Patient Instruction Booklet for the SynergEyes KC and ClearKone Hybrid Contact lenses and those prescribed by
- 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.
- Always avoid all harmful or irritating vapors and fumes while wearing lenses.
- To avoid contaminating their solution, patients should be instructed: DO NOT transfer to other bottles or
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses.
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**ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO)**

Patients should be informed that the following problems may occur:

- Stinging, burning or grittiness
- Itching
- Dryness
- Blurred vision

if any of the above occurs, a serious condition such as infection, chronic 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.

**SUMMARY OF CLINICAL STUDY**

A one-month clinical study of the SynergEyes KC Hybrid Contact Lens was conducted to assess safety and effectiveness for vision correction in daily wear for patients suffering from keratoconus and associated refractive errors of myopia, hyperopia, astigmatism, and irregular astigmatism. The study was designed to evaluate contact lens visual acuity and wearing time; and assess contact lens adverse events and loss of visual acuity. Overall Findings: A total of 62 subjects were enrolled in the study, of which 44 (71%) subjects completed, and 18 (29%) subjects were discontinued. The population demographics were similar to other contact lens studies with a female to male gender ratio of 1.4:1.0. The average age of the completed participants was 40.7 and the average age of the discontinued participants was 40.8. The average follow-up was 28.7 days for the study and 28.0 days for the 2 completed subjects and 2 discontinued subjects. One subject presented with mechanical abrasion on the apex of the cone in both eyes and discontinued. After the several days, the patient was retested in the remaining eye and found to have non-significant change in intracorneal pressure in both eyes. At the 1 week follow-up, one subject presented with edema and infiltrates in the left eye 61 days after lens dispensing. The subject presented with a right eye with small white spots on the lens surface. Eighteen (18) subjects, or 29% of the 62 dispensed subjects, were discontinued. The most common reasons for discontinuation were loss of vision (13.5%), other (16%), patient request (16%), dryness-scratching (12.5%). These rates were higher for discontinued patients (41.4%, 24.7%, and 18.7% respectively). Effect on Visual Acuity - Visual acuity for complete subjects was 20/25 or better (74.2%), 20/40 or better (83.9%). The visual acuity for discontinued subjects were 8.4%, 27.8%, 47.2%, and 52.8% respectively. Vision correction fluctuated as expected with the instability of the keratoconus cornea. One subject had a keratoconic scar on the corneal curvature from keratoconus under the contact lens contributing to the change. Five (5) completed patients and 3 discontinued patients were reported to have VA decreases of more than 2 lines of Snellen VA when comparing the contact lens VA with their best corrected VA. These findings are expected with this population. These findings are not contradictory to the SynergEyes KC Hybrid Contact Lens for Keratoconus provided satisfactory performance as expected. Discontinuation rates were somewhat higher than normal due to the nature of the subjects enrolled. There were no discontinuations for safety related reasons. Overall, the lens performance demonstrated safe and effective contact lens wear for the device being evaluated.

**FITTING**

Refer to the Professional Fitting and Information Guide for detailed information on the fitting of the SynergEyes KC & ClearKone Hybrid Contact Lens. Copies of these resources are available from: SynergEyes, Inc., Carlsbad, CA 92008 USA: Telephone: 1-760-476-9410 or FAX: 1-760-476-9400 www.synergeyes.com

**RECOMMENDED INITIAL WEARING SCHEDULE**

Although many practitioners have developed their own initial wearing schedule, the following is recommended as a guideline. Patients should be cautioned to limit the wearing schedule to the level recommended by the eyecare practitioner regardless of how comfortable the lenses feel. An initial daily wear schedule may be offered at the practitioner’s discretion.

Day 1: wear to not exceed 6 hours total
Day 2 - 6 hours total
Day 3 - 5 hours total
Day 4 - 4 hours total
Day 5 - wear to eyecare practitioner allowing during waking hours

The lenses may only be worn for daily use wear and for a period of up to 6 (6) months or as recommended by the eyecare practitioner.

A well fit lens provides for comfort and minimal movement. The effects of lid irritation on blinking and tearing may result in lens dissociation during open eye wear. Patients must be cautioned: “when in doubt, take it off.” It is important that the 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, the patient should be instructed to remove the lens, clean and rinse it and replace the lens only if the sensation continues, the lens should not be worn.

The patient should report for follow-up evaluation at the prescribed follow up schedule. The visit is best scheduled several hours after wearing the lens and the patient should report with the lens in place. This visit provides an excellent opportunity for the treatment of any problems not detected at the follow-up visit. The patient may be instructed to continue daily wear of the lens until the next scheduled follow-up visit. Upon the absence of clinical signs and complications, the patient may be instructed to continue daily wear of the lens until the next scheduled follow-up visit.

**LENS CARE DIRECTIONS**

Eye care practitioners should review lens care directions with the patient, including both basic lens care information and specific lens care recommendations recommended for the patient. Wearing and lens replacement schedules should be determined by the eyecare practitioner. Soft contact lens care products are recommended by SynergEyes. In the event that the patient does not respond to these products or this lens care system, the patient may be instructed that following disinfection with a peroxide product, the lens should be rinsed with sterile saline.

**Lens Deposits and Use of Enzymatic Cleaning Procedure**

Lens deposits cannot be removed with regular cleaners. Removing protein deposits is important for the lens and for visual acuity.

**Care for a Dehydrated Lens**

The soft poly-hema portion of the SynergEyes KC and ClearKone Hybrid Contact Lens may become dried out if left immersed in the multipurpose solution when the lenses are not being worn. If the lens sticks (does not move) or does not move freely on the eye, the patient may be instructed to continue daily wear of the lens until the next scheduled follow-up visit.

**Lubricating/Rewetting Solutions**

The eyecare practitioner may recommend a lubricating/re-wetting solution for patient use. Lubricating/ Rewetting solutions can be used to rewet (hydrate) lenses while they are being worn to make them more comfortable. Patients should be instructed to use the recommended lubricating solution after the lenses are inserted into the eye. Enzyme cleaning may be recommended by the eyecare practitioner. Enzyme cleaning removes protein deposits on the lens surface and (in some cases) helps the patient discontinue the use of antibacterial and antifungal preservatives and stops the lens from feeling gritty. Solution and lens case manufacturers may send resources to the practice to help the eyecare practitioner educate the patient on the use of enzyme cleaning solutions.

**Dry Eye**

If the lenses stick (do not move) or does not move freely, patients should report this to the eyecare practitioner. Patients should be instructed to discontinue lenses, clean and rinse it and replace with a new lens.

**REPORTING OF ADVERSE REACTIONS**

Nineteen (19) subjects, or 30.6% of the 62 dispensed subjects, were discontinued. The most common reasons for discontinuation were dry eye (61.3%), poor comfort (38.9%), poor outcome with lenses (16.7%), and ‘other’ (16.7%). "Other" reasons included: patients chosen to continue daily wear of the lens until the next scheduled follow-up visit.

**Symptoms and Possible Solutions**

- Unusual eye secretions
- Sensation of foreign body
- Inability to wear the lens
- Painful eyes
- Sensation of torn or clenched eyes
- lids
- Vision correction may be reduced
- Patients should be instructed to discontinue daily wear of the lens until the next scheduled follow-up visit.

**REPORTING OF ADVERSE REACTIONS**

All serious adverse experiences and adverse reactions observed in patients wearing SynergEyes KC or ClearKone Hybrid Contact Lenses will be reported to the manufacturer. Reporting of the device to the manufacturer is required regardless of how uncomfortable the lenses feel. Removing protein deposits is important for the well-being of the lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

**How Supplied**

Each SynergEyes Hybrid Contact Lens is supplied in a sterile glass vial. NOTE: Do not dispense the lenses or the lens care system to the patient or wear the lenses if the vial is not unbroken. The lens is shipped wet in 0.6% buffered sodium chloride solution. The vial is labeled to be used as a single lens in a 2-pack carton package. The vial is labeled with the central base curve radius, skid curve radius, dioptric power, overall diameter, lot number, and expiration date. In addition, the vial label will show icons for UV and sterilized marks. The packing slip or invoice is marked with the central base curve radius, skid curve radius, dioptric power, overall diameter, and lot number.

**Manufacture**

Do not use if package is damaged.