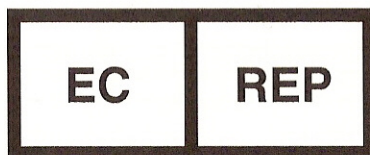


PACKAGE INSERT

FOR THE

*SynergEyes® Multifocal*  
(paflucocon D – hem-iberfilcon A)

**MULTIFOCAL  
HYBRID CONTACT LENSES FOR  
FOR DAILY WEAR**



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Molenstraat 15  
2513 BH, The Hague  
The Netherlands  
Tel: (+31) 70 345 8570  
Fax: (+31) 70 348 7299

**Australian Sponsor**  
**Emergo Asia Pacific Pty Ltd**  
**ACN 108 597 of Level 20**  
**Tower II Darling Park**  
**201 Sussex Street**  
**Sydney, NSW 2000, Australia**  
**Tel: +61 (0) 2.9006.1662**  
**Fax: +61 (0) 2.9006.1010**

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

*Important: Please read carefully and keep this information for future use.  
This package insert is intended for the eyecare practitioner, but should be made  
available to patients upon request. The eyecare practitioner should provide the  
patient with patient instructions that pertain to the patient's prescribed lens.*

## DESCRIPTION

*SynergEyes® Multifocal Hybrid Contact Lenses* are manufactured from rigid gas permeable material (paflucocon D) and SynergEyes poly-hema material (hem-iberfilcon A). The lenses are designed to have four zones on the anterior and posterior surfaces:

### Rigid Gas Permeable Material

1. The central anterior multifocal and posterior aspherical or spherical base curve zone
- ### Poly-Hema Material
2. The intermediate spherical zone
  3. The peripheral anterior edge taper and posterior bevel
  4. An edge terminus smoothly joining the anterior taper to the posterior bevel

*SynergEyes® Multifocal Hybrid contact lenses* for presbyopia are for daily wear. The center material is a thermoset fluorosilicone acrylate copolymer derived primarily from siloxane acrylate, trifluoroethyl methacrylate and methylmethacrylate with a water content of less than 1%. The peripheral skirt material is a poly-hema hydrophilic copolymer with a water content of 27%. The lenses are available as lathe cut contact lenses with a blue tint in the rigid central material. The blue material contains D&C Green No. 6. The poly-hema skirt is clear.

### Lens Parameters Available:

	Overall Lens	RGP Center	Soft Skirt
Overall Diameter (D)	14.5mm		
Central Base Curve Radius		7.10 to 8.50mm	
Base Curve Radius-Soft Skirt			1.0 to 1.3mm flatter than BCR
Optical Zone Width		7.80mm	
Center Thickness Range		0.12 to 0.30mm	
Peripheral Bevel (Blend) Radius			12.00mm
Peripheral Bevel Width			0.5mm
Dioptic Powers		+20.00 to -20.00D	
Front Surface Cylinder Power		+0.50 to +6.00D	
Near Add Powers		+1.00 to +4.00D	

### Lens Properties:

LENS CHARACTERISTICS	<i>SynergEyes® Multifocal</i> (RGP Center)	<i>SynergEyes® Multifocal</i> ( Soft Skirt)
Refractive Index	1.53	1.442(Nd at 25°C)
Luminous Transmittance(D&C Green 6) (380nm to 780nm)	>90%	95%
Wetting Angle (Receding Angle) (RGP Center)	42 <sup>0</sup>	N/A
Specific Gravity (RGP Center)	1.10	N/A
Hardness (RGP Center)	79	N/A
Oxygen Permeability (RGP Center)†	100	
Oxygen Permeability (Soft Skirt)†		9.3
Water Content (RGP Center)	<1%	
Water Content (Soft Skirt)		27%

\* Determination of the Spectral and Luminous Transmittance, ISO 8599:1994

† Method for determination of oxygen permeability: ISO/DIS 9913.1 1994. Optics and Optical instruments – Contact Lenses- Part 1: Determination of oxygen permeability and transmissibility with the Fatt method. (PHEMA Standard)

## ACTIONS

*SynergEyes® Multifocal* Hybrid contact lenses act as a refracting medium to focus light rays on the retina.

## INDICATIONS (USES)

*SynergEyes® Multifocal* (paflucocon D hem-iberfilcon A) Hybrid Contact Lenses for daily wear are indicated for use in the correction of hyperopic, myopic and astigmatic refractive error including presbyopia, in aphakic and not aphakic, non-diseased eyes. The lenses are indicated for daily wear for the correction of up to +20.00 and -20.00 D in eyes with astigmatism up to 6.00 D. For presbyopia, add powers from +1.00 to +4.00D. The lenses may be disinfected using only a chemical disinfecting system compatible with both hydrogel and rigid gas permeable lenses.

## CONTRAINDICATIONS (REASONS NOT TO USE)

**DO NOT USE *SynergEyes® Multifocal* Hybrid contact lenses when any of the following conditions exist:**

- Acute and sub-acute inflammations 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 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).
- If 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 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 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 lens and promptly contact his or her eyecare practitioner.

## PRECAUTIONS

### Special Precautions for Eyecare Practitioners:

- Clinical studies have demonstrated that contact lenses manufactured from the SynergEyes material are safe and effective for daily wear. Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the *SynergEyes® Multifocal* contact lens were 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 continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.
- Patients who wear aspheric contact lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Standard fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The poly-hema skirt of the lens may absorb this dye and become discolored. Whenever standard fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use. The fitting evaluation should be performed using large molecule fluorescein.
- 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 instruct the patient to remove the lenses immediately if the eye becomes red or irritated.

### **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.
- 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® Multifocal 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 period of drying may damage the poly-hema lens skirt. Follow the lens care directions on *Care for a Dried Out Lens* if the lens skirt becomes 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 nonmovement of the lens continues, the patient should be instructed to immediately consult his or her eyecare practitioner.
- Always wash and rinse hand 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 contact lenses with 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 Instruction Booklet for the *SynergEyes® Multifocal Hybrid* contact lenses and those prescribed by the eyecare practitioner.
- Never wear lenses beyond the time recommended by the 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 the eyecare practitioner about wearing lenses during sporting activities.
- 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.

### **ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO)**

Patients should be informed that 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 the patient notices any of the above, he or she should be instructed to:

### **IMMEDIATELY REMOVE THEIR 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, the patient 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.

### **SUMMARY OF CLINICAL STUDY**

A three month clinical study of the SynergEyes® Hybrid Contact Lens was conducted to assess safety and effectiveness for vision correction in daily wear that included subjects with nearsightedness, farsightedness, and astigmatism. Included in this population were 13 subjects (13 eyes) that fitted for monovision in one eye for near vision correction. 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 107 subjects in which 61 (57%) subjects completed, and 46 (43%) subjects were discontinued.

The population demographics were similar to previous contact lens studies with a female to male gender ratio of 2.3 to 1.0. The average age of the completed and discontinued subjects was 42.1 with an age range of 12 years to 60 years of age.

#### *Safety:*

There were no serious adverse events reported during the trial. There was one subject (2 eyes) discontinued for complications of corneal abrasions, described as “poor outcome with lenses”. The subject was treated and the condition resolved in both eyes. Additional reasons for discontinuation included poor comfort (32.6%), loss of interest (28.3%), poor vision (13.0%), handling difficulty (2.2%), and other (23.8%). “Other” reasons included unrelated medical conditions (4.3%), non-compliance (8.7%), poor outcome with lenses (4.3%) including the above described subject, and undefined ( 6.5%).

#### *Efficacy:*

Visual Acuity- Final visual acuity for completed subjects was 20/20 or better (40.2%), 20/25 or better (65.6%), 20/30 or better (82.0%), and 20/40 or better (90.2%). No visual acuity was lost during the course of the study. Visual acuity was reported worse than 20/40 for 9.8% (12/122) of the completed eyes. Of those 8 eyes were fitted for near vision for monovision correction.

Wearing Time- Over the study period the average daily wearing time reported by completed patients was 11.4 hours per day.

#### **Conclusion:**

The SynergEyes® Hybrid Contact Lens provided satisfactory performance as expected. Discontinuation rates were somewhat higher than normal due to the reasons cited above. There were no discontinuations for safety related reasons. Overall, the lens performance demonstrated safe and effective use of the device for its intended use.

#### **FITTING**

Refer to the Professional Fitting and Information Guide for detailed information on the fitting of the *SynergEyes® Multifocal* hybrid contact lens for daily wear. Copies are available from;

SynergEyes, Inc.  
Research Center Plaza  
2232 Rutherford Rd.  
Carlsbad, CA 92008

1-760-476 9410  
1-760-476 9340 FAX

#### **RECOMMENDED INITIAL WEARING SCHEDULE**

Although many practitioners have developed their own initial wearing schedules, the following sequence

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.

It is ideal for the patient to start with full daily wear the first day. 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.

Patients must be cautioned; “when in doubt, take it out”. 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. 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 after several hours of wear and the patient 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, the patient 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 the practitioner’s discretion.

Day 1	two periods of wear not to exceed 6 hours total
Day 2	6 hours
Day 3 - Day 5	8 hours
Day 6	full waking hours

## LENS CARE DIRECTIONS

Eyecare practitioners should review lens care directions with the patient, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient:

### 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 recommended system of lens care, which is chemical (not heat) 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, enzyme and disinfect your lenses according to the schedule prescribed by your eyecare practitioner. The use of an enzyme or 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.

**The lens care products listed below are recommended by the manufacturer for use with your SynergEyes® Multifocal Hybrid contact lenses.**

SYSTEM PROCESS	CHEMICAL (not heat) DISINFECTION SYSTEM
Cleaning	OPTI-FREE® EXPRESS® Multi-purpose, (OPTI-FREE® Supra CLENS® on direction of eyecare practitioner) <b>OR</b> Clear Care®
Disinfection	OPTI-FREE® EXPRESS® Multi-purpose, (OPTI-FREE® Supra CLENS® on direction of eyecare practitioner) <b>OR</b> Clear Care®
Rinsing	OPTI-FREE® EXPRESS® Multi-purpose
Storage	OPTI-FREE® EXPRESS® Multi-purpose, (OPTI-FREE® Supra CLENS® on direction of eyecare practitioner) <b>OR</b> Clear Care®
Enzyme	OPTI-FREE® Supra CLENS® on direction of eyecare practitioner
Lubrication	Clerz® Plus

OPTI-FREE® EXPRESS® Multi-purpose, Supra CLENS® and Clerz® Plus are registered trademarks of Alcon Laboratories, Inc. Clear Care® is a registered trademark of Ciba Vision, Inc.

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 the instructions.

## 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 M 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 the 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® Multifocal Hybrid contact lenses cannot be heat (thermally) disinfected.*

### 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 a lubricating/rewetting solution for your use. Lubricating/Rewetting solutions can be used to rewet (lubricate) your lenses 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 cleaning and disinfecting. For enzyme cleaning the recommended care product is SupraCLENS®. The recommended frequency for use of SupraCLENS® is once every seven days (1 night per week). Carefully follow the instructions in the enzymatic cleaning labeling.

### 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 poly-hema portion of the *SynergEyes® Multifocal* contact lens may become dried out if left exposed to air while the lenses are off the eye. Rehydrate 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 prior to handling. Properly clean, rinse and disinfect the lenses prior to reinsertion.

## 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.**

## HOW SUPPLIED

Each *SynergEyes® Multifocal* Hybrid contact lenses for presbyopia with and without hyperopia and myopia, with and without astigmatism lens is supplied in a sterile glass vial. The lens is shipped wet in 0.9% buffered sodium chloride solution.

The vial label is marked with base curve, diameter, power, lot number and expiration date. In addition, the vial label will show icons for Rx Only and Sterile marks.

The packing slip or invoice is marked with the central equivalent base curve radius, skirt curve radius, dioptric power, and lot number.

## REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing *SynergEyes® Multifocal* Hybrid contact lenses or experienced with the lens should be reported to:

SynergEyes, Inc.  
Research Center Plaza  
2232 Rutherford Rd.  
Carlsbad, CA 92008

1-760-476 9410  
1-760-476 9340 FAX



Manufactured and Marketed by  
SynergEyes, Inc.  
Research Center Plaza  
2232 Rutherford Rd.  
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