

Important: This package insert is effective as of December 2002 and supersedes all prior inserts for the products described below. Please read carefully and keep this information for future use. This package insert is intended for the eye care professional, but should be made available to patients upon request. The eye care professional should provide the patient with appropriate instructions that pertain to the patient's prescribed lenses. Copies of this package insert are available without charge from CIBA Vision Corporation by calling CIBA Vision Customer Service at 1-800-241-5999 or [download from our web-site at www.cibavision.com](http://www.cibavision.com). CIBA Vision makes available a Patient Instruction Booklet that is recommended to be given to the patient.



CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED EYE CARE PROFESSIONAL.

PRODUCT DESCRIPTION

Lens Material

The lens material, pHEMA, is a hydrophilic copolymer of 2-hydroxyethyl methacrylate and 2-ethoxyethyl methacrylate.

WildEyes soft contact lenses are made by modifying the uncolored lens by affixing a colored pigment on that portion of the front surface of the lens which corresponds to the iris. The colored pigments consist of the following color additives listed in the color additive provisions of 21 CFR: iron oxides, titanium dioxide, [phthalocyaninato (2-)] copper, chromium oxide greens, phthalocyanine green, carbazole violet, mica coated with iron oxide and mica coated with titanium dioxide. The pigments are not removed by the lens handling and cleaning/disinfecting procedures. The optical performance characteristics are not altered by the lens coloring process.

Lens Properties

The Physical Properties of the lens are:

- Specific Gravity: 1.178
- Refractive Index: 1.412
- Light Transmittance: 95% minimum
- Surface Character: Hydrophilic
- Water Content: 55%
- Optical Zone: 5mm
- Oxygen Transmissibility (Dk/L): 32.2x10⁻⁹ ml O₂/cm²/sec mm Hg @ 35°C

(Dr. Irving Fatt Method)

Available Lens Parameters

WildEyes soft contact lenses are hemispherical shells of the following dimensions:

- Spherical Lens Parameters:
- Chord Diameter: 12.0 to 15.0 mm
 - Center Thickness: Varies with power. Typically 0.05mm for minus lenses increases with increasing plus power.
- Base Curve: 7.80 to 9.00 mm
- Powers: -20.00 Diopters to +20.00 Diopters for Daily Wear
- Prism Ballasted: .25D/0D

ACTIONS

When placed on the cornea, a hydrated WildEyes spherical soft contact lens acts as a refracting medium to focus light rays on the retina. The WildEyes contact lens acts to alter the apparent color of the eye.

INDICATIONS (USES)

Vision Correction:

WildEyes (pHEMA) soft (hydrophilic) contact lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may be worn by persons who exhibit refractive astigmatism of up to 2.0 diopters that does not interfere with visual acuity. The lens ranges in power from plano to -6.0 Diopters for daily wear.

Wearing Schedule:

The lenses may be prescribed for Daily Wear in aphakic and/or non-aphakic persons for cleaning and disinfection, as recommended by the eye care professional.

CONTRAINDICATIONS (REASONS NOT TO USE)

WildEyes soft contact lenses are contraindicated when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye.
- Active disease, injury or abnormality affecting the cornea, conjunctiva or eyelids.
- Microbial infection.
- Insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity, if not-aphakic).
- Use of medication that is contraindicated, including eye medications.
- Patient history of recurring eye or eyelid infections including styes, or of adverse effects associated with contact lens wear, or of intolerance or abnormal ocular response to contact lens wear.
- History of patient non-compliance with contact lens care and disinfection regimens, wearing restrictions, wearing schedule or follow-up visit schedule.
- Patient's inability or unwillingness because of age, infirmity or other mental or physical conditions or an adverse working or living environment, to understand or comply with any lens care requirements, warnings, precautions, restrictions or directions.
- Allergy to any ingredient such as mercury or Thimerosal in a solution which must be used to care for the lens.
- Patients who require only vision correction and who would not, or could not, adhere to a recommended care system for lenses or who are unable to place and remove lenses should not be provided with them.
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- If eyes become red or irritated.
- Any active corneal infection (bacterial, fungal, or viral).
- Serious eye injury and loss of vision may result from problems associated with wearing contact lenses and using contact lens care products. Therefore, after a thorough eye examination, including appropriate medical background, patients must be fully apprised by the prescribing practitioner of all the risks associated with contact lens wear.

Since eye injury can develop rapidly, it is most important that patients be instructed in the possible signs or symptoms of problems and the need to remove the lenses and be examined by the prescribing eye care practitioner or a corneal specialist immediately if they experience any symptoms such as those listed below under the ADVERSE EFFECTS Section. (Practitioners examining patients presenting such symptoms should refer to the Professional Fitting Guide and Patient Instruction Booklet).

WARNINGS

Advise patients of the following warnings pertaining to contact lens wear:

- Serious eye injury, scarring of the cornea, and loss of vision may result from problems associated with wearing contact lenses and using contact lens care products. To reduce these risks, emphasize to the patient the need for strict compliance with the lens care regimen including hand washing, proper lens disinfection, cleaning of the lens case, wearing restrictions, wearing schedules, and follow-up visit schedules.
- Eye problems including corneal ulcers can develop rapidly and lead to loss of vision. Instruct patients at the dispensing visit and subsequent visits to immediately remove their lenses and promptly contact their eye care practitioner if they should experience eye discomfort, foreign body sensation, excessive tearing, vision changes, redness of the eye or other problems with their eyes.
- Non-compliance with the manufacturer's labeled lens care instruction may put the patient at significant risk of developing a serious eye infection.
- Tap water, distilled water, or homemade saline solution should NOT be used as a substitute for any component in the lens care process. The use of tap and distilled water has been associated with Acanthamoeba keratitis, a corneal infection that is resistant to treatment and cure.
- Smoking increases the risk of corneal ulcers for contact lens users especially when lenses are worn overnight or while sleeping.
- The Packaging of This Product Contains Dry Natural Rubber.

PRECAUTIONS

In prescribing contact lenses, the Precautions should be carefully observed. It is also strongly recommended that the practitioner review with the patient the appropriate Patient Instruction Booklet available from CIBA Vision prior to dispensing the lenses and ensure that the patient understands it contents.

- Due to the small number of patients enrolled in clinical investigation of lenses, not all refractive powers, design configurations, or lens parameters available in the lens material are evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care 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 eye care practitioner.
- Contact lens wear may not be suitable for certain occupations or, in other instances, may require eye protection equipment. Therefore, the patient should always inform his/her employer that contact lenses are being worn. Environmental fumes, smoke, dust, vapors, and windy conditions must be avoided in order to minimize the chances of lens contamination or physical trauma to the cornea.
- Eye injury from irritation or infection and damage to lenses may result from lens contamination. The patient should be instructed to refrain from using saliva or anything other than the recommended solution for lubricating or wetting lenses. The patient should also be informed to wash and rinse hands before handling contact lenses at all times.
- Eye care practitioners should instruct the patient to remove the lenses immediately if the eyes become red or irritated.
- The patient should be informed that contact lenses should not come into contact with any cosmetics, lotions, soaps, creams, hairsprays or deodorants, that it is best to put on lenses before putting on makeup, and that water-based cosmetics are less likely to damage lenses than oil-based products.
- The patient should be informed not to use aerosol or pump products, such as hairspray, while the lenses are worn since liquid and vapors may damage the lens.
- The patient should be instructed to handle the lenses carefully and avoid dropping or touching them with fingernails, which can cause contamination or damage of the lens. The patient should also be told that if the lens becomes nicked or torn, it should not be worn.
- Tweezers or other tools should not be used by patients to remove a lens from the lens container. The lens should be poured into the hand. Lenses should be cleaned in the palm of the hand rather than between thumb and finger.
- Patients should be instructed on and be able to demonstrate prompt removal of the lenses.
- Fluorescein should not be used while the lenses are on the patient's eye. The lenses absorb this dye and become discolored. Fluorescein in the eye should be thoroughly flushed with a sterile saline solution recommended for in-eye use and a new lens should be reinserted only after at least one hour.
- A lens must move freely on the eye for a proper fit. For further information, refer to the appropriate WildEyes soft contact lens Professional Fitting Guide.
- The patient should be instructed to inform his or her physician that contact lenses are worn and to consult his or her eye care practitioner before using any medication in the eye.

- Exposure to water while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection, including but not limited to Acanthamoeba keratitis.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.
- Certain medications such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness may cause dryness of the eye, increased lens awareness or blurred vision. Should these conditions exist, proper remedial measures should be prescribed. Depending on the severity, this could include the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medication is being used.
- A patient who has been prescribed WildEyes contact lenses on a daily wear schedule should be cautioned to remove the lenses before sleeping.

ADVERSE EFFECTS:

Potentially serious complications are usually accompanied by one or more of the following signs and symptoms:

- Foreign body sensation
- Excessive watering (tearing) of the eyes or other eye secretions including mucopurulent discharge
- Redness of the eyes
- Photophobia (light sensitivity)
- Burning, stinging, itching or other pain associated with the eyes
- Comfort is less compared to when lens was first placed on eye
- Poor visual acuity
- Blurred vision, rainbows, or halos around objects
- Feeling of dryness

If the patient notices any of the above signs or symptoms, he or she should be instructed to **IMMEDIATELY REMOVE THE LENSES.**

- If the discomfort or problem stops, look closely at the lens.
 - If the lens is in any way damaged, DO NOT put the lens back in the eye. Discard the lens.
 - If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops, clean, disinfect and reinsert the lens.
- If the discomfort or problem continues after removal of the lens or upon reinsertion, immediately remove lenses and promptly contact his or her eye care professional. The eye care professional must determine the need for examination, treatment or referral without delay.
- Patients should be informed that a serious condition such as infection, corneal ulcer, corneal vascularization or iritis may be present and may progress rapidly. Less serious reactions, such as abrasions, epithelial staining and bacterial conjunctivitis should be treated appropriately to avoid complications. Additionally, contact lens wear may be associated with ocular changes that require consideration of discontinuation or restriction of wear. These include but are not limited to local or generalized corneal edema, epithelial microcysts, epithelial staining, infiltrations, neovascularization, endothelial polymegathism, tarsal papillary changes, conjunctival infection or iritis.

ADVERSE EFFECT REPORTING

If a patient experiences any serious adverse effects associated with the use of WildEyes (pHEMA) contact lenses, eye care professionals please notify CIBA Vision Corporation, Technical Consultation Services at 1-800-241-7468.

FITTING GUIDES AND PATIENT INFORMATION BOOKLETS

- The lens must move adequately on the eye for a proper fit and continued health of the eye. If the fit is judged to be too tight or steep, the patient must be refit into a lens that provides the criteria of a well-fitted lens.
- Conventional methods of fitting contact lenses apply to WildEyes soft contact lenses. For a detailed description of the fitting technique, refer to the appropriate CIBA Vision Professional Fitting Guide.
- It is strongly recommended that the patient be provided appropriate Patient Information Booklet available from CIBA Vision and understands its contents prior to dispensing the lenses.
- Copies of Fitting Guides and Patient Information Booklets for WildEyes are available without charge from: CIBA Vision Corporation, Duluth, Georgia USA 30097 or by calling a CIBA Vision customer service representative at 1-800-241-5999.

LENS REPLACEMENT SCHEDULES

In a planned replacement program, the replacement schedule is determined by the eye care professional based upon the patient's physiological condition. CIBA Vision recommends frequent replacement of WildEyes lenses at intervals of every year. The eye care professional may determine a replacement schedule greater or less than these suggested intervals based upon clinical examination of the patient, professional judgment, and clinical experience with the lenses because individual responses to contact lenses vary.

WEARING SCHEDULES

The wearing schedule should be determined by the eye care professional. CIBA Vision recommends that contact lens wearers see their eye care professional twice each year or, if directed, more frequently.

The maximum suggested wearing time each day should be determined by the eye care professional based upon the patient's physiological eye condition because individual responses to contact lenses vary.

The eye care professional may prescribe the lens for frequent replacement with cleaning, disinfection and scheduled replacement. When prescribed for:

DAILY WEAR: There may be a tendency for the daily wear patient to overwear the lenses initially. Therefore, the importance of adhering to a proper initial daily wearing schedule should be stressed to these patients. The wearing schedule should be determined by the eye care professional and provided to the patient. These lenses may be worn in the Frequent Replacement Program.

Suggested Daily Wear Adaptation Scheduled

Day	Wear Time (hours)
1	4
2	5
3	6
4	7
5	8
6	9
7	10
8	All waking hours

LENS CARE DIRECTIONS

Basic Instructions for Lens Cleaning and Disinfection:

When lenses are dispensed, the patient must be provided with appropriate and adequate instructions and warnings for lens care handling.

The eye care professional should recommend appropriate and adequate procedures and products for each individual patient in accordance with the particular lens wearing schedule and care system. The specific instructions for such products and the particular characteristics of the patient should also be taken into consideration.

The basic general instructions for general lens care are as provided below:

- Always wash and rinse your hands before handling your contact lenses.
- The lenses should be cleaned and disinfected before reinsertion into the eye. Use a suggested chemical (not heat) lens care system recommended by the practitioner since heat may cause discoloration.
- Use and follow the instructions of lens care products intended for use with soft (hydrophilic) contact lenses.
- Always use lens care solutions before they reach the expiration date.
- Always keep the lenses completely immersed in the recommended storage solution when they are not being worn (stored).
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.

CHEMICAL (NOT HEAT) DISINFECTION

Use any approved solution regimen recommended by the eye care practitioner. Follow the manufacturer's directions provided with those solutions.

- Clean and rinse one lens first (always the same lens first to avoid mix-ups) and put the lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- Always rinse the lenses thoroughly to remove the cleaning solution.
- Disinfect lenses using the chemical (not heat) disinfection system which the eye care practitioner has recommended. Do not heat the disinfecting solution and lenses.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear.
- Thoroughly rinse lenses with sterile fresh rinsing solution before inserting and wearing.
- If the lenses have been stored in the unopened case for more than 24 hours, disinfect immediately before wearing or at least once a week.
- To prevent contamination and to help avoid serious eye injury, always empty and rinse lens case with fresh rinsing solution and allow to air dry.

CLEANING PROCEDURE

Enzyme cleaning may be recommended by the eye care practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits can not be removed with regular cleaners. Removing protein deposits is important for the 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 with solutions recommended by the lens case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or eye care professional.

Refer to the PRECAUTION Section for further information on lens care and handling.

CARE FOR A DEHYDRATED LENS

If a soft (hydrophilic) contact lens is exposed to air while off the eye, it may become dry and brittle. Dehydrated lenses should be disposed of. Therefore, it is important that the patient always have a pair of new sterile replacement lenses available.

Eye care practitioners should review the following information on rehydrating the lens with the patient:

- Handle the lens carefully.
- Place the lens in a storage case and soak the lens in a recommended rinsing and storing solution for at least an hour until it returns to a soft state.
- Clean and disinfect the rehydrated lens using a recommended lens care system.
- If, after soaking, the lens does not become soft, the lens should not be used until examined by the eye care professional.

CARE FOR A STICKING LENS:

If the lens sticks (stops moving) or begins to dry on the eye, the patient should be instructed to apply several 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 several minutes, the patient should be instructed to immediately consult the eye care professional.

IN OFFICE USE OF TRIAL LENSES

Eye care professionals should educate contact lens technicians concerning proper use of trial lenses.

Each contact lens is shipped sterile in a sealed vial containing isotonic, phosphate buffered saline solution. Hands should be thoroughly washed, rinsed and dried with a lint free towel prior to handling a lens. In order to insure sterility, the glass vial should not be opened until immediately prior to use. For fitting and diagnostic purposes, the lenses should be disposed of after a single use and not be re-used from patient to patient.

EMERGENCIES

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should **flush eyes immediately with tap water and call or visit the eye care professional or a hospital emergency room without delay.**

HOW SUPPLIED

Each lens is sterilized and supplied in a glass vial containing sterile, isotonic, buffered saline solution. The glass vial is marked with the base curve, diameter, dioptric power, design, manufacturing lot number of the lens and expiration date.

ADDITIONAL INFORMATION

For answers to your questions about WildEyes soft contact lenses or to report any adverse reactions, eye care professionals contact our Technical Consultation Services at 1-800-241-7468 during regular business hours. For additional copies of the Eye Care Professional Package Insert or Professional Fitting Guide and Patient Instruction Booklet, contact our Customer Service Department at 1-800-241-5999.

PATENT PROTECTED

U.S. Patents: 4,668,240; Des. 416,923; Des. 421,617; Des. 416,924

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