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. CIBA Vision makes available a Patient Instruction Booklet that is recommended to be given to the patient.

PACKAGE INSERT for DURASOFT® 3 Spherical, Clear, Handling Tint, Colors Complements® and ColorBlends®;
DURASOFT 3 Spherical, Clear, Handling Tint, ColorBlends®;
DURASOFT 3 UV Spherical, Clear, Handling Tint, Colors and Complements:
DURASOFT 3 UV OptiFit Toric: Clear, Handling Tint, Colors and Complements:

CIBA Vision
A Novartis Company

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

DESCRIPTION
DURASOFT 3 Spherical and OptiFit Toric Soft (hydrophilic) Contact Lenses with or without UV absorber are available uncoated and with a Handling Tint. CIBA Vision has the authority to manufacture DURASOFT 3 Spherical and OptiFit Toric Soft (hydrophilic) Contact Lenses with or without UV absorber in accordance with your CIBA Vision representative or your eye care practitioner for availability.

The optical and performance characteristics are not altered by the lens coloring process.

PRODUCT DESCRIPTION
Lens Material
The lens material, perfluorooctyl fluoride, is a hydrophilic copolymer of 2-hydroxyethyl methacrylate and 2-ethylhexyl methacrylate.

The DURASOFT 3 UV Handling Tint lens and the DURASOFT 3 UV Colors Spherical and OptiFit Toric soft contact lenses contain proprietary UV-absorbing monomer (C2VBT) which has been incorporated into the polymer matrix of the lens to absorb ultraviolet (UV) light. The DURASOFT 3 Spherical Colors and Spherical and OptiFit Toric and DURASOFT 3 Colors Complements (perfluorooctyl fluoride) Hydrophilic Contact Lenses are made by modifying the uncoated DURASOFT 3 Spherical, Clear and OptiFit Toric, Clear Soft (hydrophilic) Contact Lenses with UV by adding a color pigmented layer on that portion of the front surface of the lens which corresponds to the insides of the lens. The DURASOFT 3 OptiFit Toric (perfluorooctyl fluoride) hydrophilic contact lenses are made by modifying the DURASOFT 3 lens by adding a colored pigment on the front surface of the lens to act as a unique orientation mark identified as (OptiMark®). The colored pigments consist of iron oxides, titanium dioxide, perfluorooctyl fluoride or carbon black, and carbazole violet. The pigment in the Handling Tint lens is either phthalamycin green or carbazole violet. The pigments are not removed by lens handling and cleaning and the optical and performance characteristics are not altered by the lens coloring process.

Lens Properties
The Physical Properties of the Lens
Specific Gravity: 1.178
Water Content: 55%
Refractive Index: 1.412
Light Transmittance: 99%
Surface Character: Hydrophilic
Water Content: 55%
Optical Zone: (DURASOFT 3 Colors UV) 5mm
Optical Zone: (DURASOFT 3 Handling Tint UV) 9mm to 5mm (varies with power)
UV Transmittance: 0-10% in the ultraviolet portion of the spectrum (250-400nm), averaged for the visible spectrum
Oxygen Transmissability: DL/32<2.10 x 10^-6 mol/ cm² sec mm Hg @ 35ºC

Available Lens Parameters
Available Lens Parameters

DURASOFT 3 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 Diptors to +20.00 Diptors for Daily Wear -30.00 Diptors to +20.00 Diptors for Extended Wear

DURASOFT 3 OptiFit Toric Lens Parameters:

Chord Diameter: 12.0 to 15.0 mm
Center Thickness: Varies with power. Typically 0.07mm for minus lenses increases with increasing plus power.
Base Curve: 7.80 to 9.50 mm
Powers: -30.00 Diptors to +20.00 Diptors for Daily Wear -30.00 Diptors to +20.00 Diptors for Extended Wear
Cylinder: -0.75 Diptors to -6.00 Diptors
Prism Ballasted:
Axis: 0° to 180° in 1° steps

DURASOFT 3 Handling Tint Toric Parameters:

Base Curve: 7.80 to 9.00 mm
Powers: -30.00 Diptors to +20.00 Diptors for Daily Wear -30.00 Diptors to +20.00 Diptors for Extended Wear
Cylinder: -0.75 Diptors to -6.00 Diptors
Prism Ballasted:
Axis: 0° to 180° in 1° steps

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 discontinue lens use and seek immediate medical attention. The patient need be examined by the prescribing eye care practitioner or a corneal specialist immediately if they experience any symptoms such as eye redness, pain, or change in vision.

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

SERIOUS EYE INJURY, SCARING 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 handling plain water, proper lens disinfection, cleaning, wearing schedules.

Eye problems including corneal ulcers can develop rapidly and if left untreated, lead to loss of vision. Instruct patient to discontinue use and seek medical attention if they experience any symptoms such as eye redness, pain, or change in vision.

UV absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear such as UV absorbing goggles or sunglasses, because they are not designed to protect the entire surrounding area. You should continue to use UV absorbing eyewear as directed.

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, or homemde 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 was 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.
tolerate the same or another lens on a daily wear basis. Patients should be carefully evaluated for extended wear prior to prescription and dispensing and practitioners should conduct early and frequent follow-up examinations to determine corneal response to extended wear.

• To prevent contamination and avoid serious eye injury, the patient should be instructed to: avoid touching the lens surfaces with hands that have not been washed, to avoid storage of lenses in a sink, by a window, or in a location where they might be exposed to contamination, and to use prescribed storage solutions and disinfectants.

• 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 medications or over-the-counter medication.

• 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, and oral contraceptives may cause drying 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 discontinuation of contact lens wear while such medication is being used.

• A patient who has been prescribed DuraSoft 3 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 indicating mucopurulent discharge
• Redness of the eyes
• Photophobia (light sensitivity)
• Burning, stinging, irritation, or other pain associated with the eyes
• Blurred vision, halos, or heavy eyes
• Foreign body sensation
• Blurred vision, rainbows, or halos around objects
• Feeling of dryness

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

• If the discomfort or problem stops, look closely at the lens and:
  - If the lens is in any way damaged, DO NOT put it back in the eye. Discard the lens.
  - If the lens has dirt, an eyelash, or other foreign object on it, or if the problem stops, clean, disinflect and reininsert the lens.

• If the discomfort or problem continues after removal of the lens or upon reininsertion, immediately remove the lens 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 wearing of the lens. These include but are not limited to local or generalized corneal edema, epithelial microcysts, epithelial staining, inflammations, 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 DuraSoft 3 (phemfilcon A) contact lenses, eye care professionals please notify CIBA Vision Technical Consulting Services at 1-800-241-7468.

FITTING GUIDES AND PATIENT INFORMATION BOOKLETS
The lens must be made adequately to fit and provide continued health of the eye. When prescribing DuraSoft 3 lenses for extended wear, it is important to reevaluate the lenses fit for adequate movement at various time intervals and to allow the patient sleeps while wearing lenses. This reevaluation should include a follow-up visit as soon as possible after the patient awakens, as well as at other times of the day. If the fit is judged to be too tight or loose, 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 DuraSoft 3 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 from CIBA Vision and understands its contents prior to dispensing the lenses.

• Copies of Fitting Guides and Patient Information Booklets for DuraSoft 3 lenses 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.

LENSES 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 DuraSoft 3 lenses at intervals of six months. The eye care professional may prescribe 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 condition because individual responses to contact lenses vary.

The eye care professional may prescribe the lens for frequent replacement with cleaning, disinfection and storage for up to seven days. When prescribed for frequent replacement, the lens may be disinfected using a chemical (not heat) disinfection system.

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.

EXTENDED WEAR:
(Greater than 24 hours or white aslept) The wearing schedule should be determined by the prescribing eye care practitioner for each individual patient, based upon a full examination and patient history as well as the practitioner’s experience and professional judgment.

CIBA Vision recommends beginning extended wear patients with the recommended initial daily wear schedule, followed by a period of daily wear and then the gradual introduction of extended wear one night at a time, unless individual considerations indicate otherwise. The eye care professional should examine the patient in the early stages of extended wearing and provide detail corneal responses. The lenses must be removed, cleaned and disinfected or disposed of and replaced with a new lens, as determined by the prescribing eyecare professional. (See the factors discussed in WARNING Section). Once removed, a lens should remain out of the eye for a period of rest overnight or longer, as determined by the prescribing eyecare professional.

LENSES CARE DIRECTIONS
Basic Instructions for Lens Cleaning and Disinfection:
When lenseduring replacement with cleaning, disinfection and storage for up to seven days. When prescribed for frequent replacement, the lens may be disinfected using a chemical (not heat) disinfection system.

CIBA Vision recommends beginning extended wear patients with the recommended initial daily wear schedule, followed by a period of daily wear and then the gradual introduction of extended wear one night at a time, unless individual considerations indicate otherwise. The eye care professional should examine the patient in the early stages of extended wearing and provide detail corneal responses. The lenses must be removed, cleaned and disinfected or disposed of and replaced with a new lens, as determined by the prescribing eyecare professional. (See the factors discussed in WARNING Section). Once removed, a lens should remain out of the eye for a period of rest overnight or longer, as determined by the prescribing eyecare professional.

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 reininsertion into the eye. A suggested chemical (not heat) lens care system recommends 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.

• Keep the lenses completely immersed in the recommended storage solution when they are not being worn (stored).

In the Frequent Replacement Program, CIBA Vision recommends that sterile solutions be used in the soft lens care system. Sterile non- preserved solutions should be used only if the patient is allergic to preservatives. When used, sterile non-preserved solutions must be discarded after the time specified in their label directions.

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.

LENSES 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 lens care system. Sterile non-preserved solutions must be used only if the patient is allergic to preservatives. When used, sterile non-preserved solutions must be discarded after the time specified in their label directions.

U.S. AND FOREIGN PATENT PENDING
US Corporate Offices:
CIBA Vision Corporation
11480 Corporate Center Dr.
Duluth, Georgia USA 30097

Date/Part No.: December 2002

PATENT PROTECTED
U.S. Nos.: 4,976,550; 4,414,477; 4,720,188; 4,704,017; 4,582,407; 4,328,269; 4,312,725; 4,518,089; 4,549,794; 4,182,802; 4,111,535; 4,190,079; 4,668,240; 5,029,898

FR Nos.: 0346302; 0498835; 0158999; 0817337; 0440017

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AU No.: 620886, 636679; 569669; 634624

JP No.: 2685319; 2011141; 1702789; 172962; 2695056

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