

IMPORTANT: This package insert is effective as of April, 2003 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. 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 copy from our website at www.cibavision.com.** The eye care professional should provide the patient with the patient instructions that pertain to the patient's prescribed lenses. CIBA Vision makes available a Patient Instruction Booklet which is recommended to be given to the patient.

R Only

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

DESCRIPTION

Precision UV (vasurfilcon A) soft (hydrophilic) contact lenses for daily and extended wear vision correction with UV protection, can be prescribed on a frequent replacement wearing schedule or disposable wearing schedule. For disposable wear, the lens wearing time prescribed by the eye care professional is for extended wear from 1 to 7 days/6 nights of continuous wear. Patients should be instructed to dispose of the contact lenses at each removal and to use lens care products only on an emergency basis.

PARAMETER	RANGE	AVAILABILITY
Chord Diameter	----	14.4 mm
Nominal Center Thickness	Minus Lens Plus Lens	0.09 - 0.17 mm‡ 0.22 - 0.41 mm
Base Curve	----	8.4, 8.7 mm
Powers	-10.00D to +8.00D -16.00D to +10.00D 0.50D steps over +5.00 to -6.00D	

The lens material, vasurfilcon A, is a copolymer of methyl methacrylate, vinyl pyrrolidone, and other methacrylates with the addition of the proprietary UV absorbing monomer UVAM. The Precision UV lens is either not tinted or locator tinted (C.I. #69825 or C.I. #61565) for easier handling.

WARNING:

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.

LENS PROPERTIES:

The physical properties of these lenses are:

Refractive Index	1.379 @ 25°C
Surface Character	Hydrophilic
Water Content	74%
Oxygen Permeability*	38.9 x 10 ⁻¹¹
Light Transmittance	a) Visible (400-800 nm) >97% b) UV (250-400 nm) ‡ UVA (315-380 nm) UVB (280-315 nm)
	+2.00 5.7 +2.00 2.6 +1.00 8.1 +1.00 5.3 -4.00 12.0 -4.00 8.4 -10.00 17.3 -10.00 13.8

* (cm²/sec)(ml O₂/ml x mmHg) at 35°C (by the Fatt method)

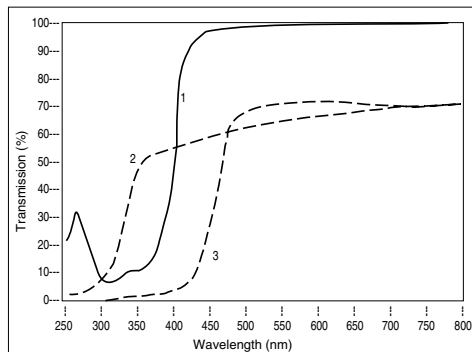
Figure 1 illustrates the transmittance of a typical Precision UV lens, a human cornea and a human lens.

Curve 1 represents the transmittance of a 0.09 mm nominal center thickness Precision UV contact lens.

A small transmittance peak appears in Curve 1 in the 250-290 nm range. This peak is located in the waveband of ultraviolet radiation (250-290 nm) that is absorbed by the earth's atmosphere. Curves 2 and 3 represent the transmittance characteristics of a human cornea from a 24 year-old person and a human lens from a 25 year-old person, respectively.

FIGURE 1

Typical Transmittance Profile of Precision UV (vasurfilcon A) Hydrophilic Contact Lens vs. a Human Cornea and a Human Lens.



1. Precision UV Contact Lens - 10.00D; nominal center thickness 0.09 mm. ‡
2. Human cornea from a 24 year-old person as described in Lerman, S., Radiant Energy and The Eye, MacMillan, New York, 1980, p.58, figure 2-21.
3. Human crystalline lens from a 25 year-old person as described in Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p.19, figure 5.

ACTIONS

When placed on the cornea, the hydrated Precision UV contact lens acts as a refracting medium to focus light rays on the retina. The thinnest Precision UV lenses (-9.00D to -16.00D) block 83% UVA radiation and 86% UVB radiation averaged across the spectrum. The UV radiation blockage of Precision UV lenses will increase for thicker lenses. For the most commonly prescribed corrective powers (+2.00D to -4.00D) the blockage is on average 91% UVA and 95% UVB. ‡

‡ This referenced data was determined from "Methods for Determining Ultraviolet Transmission of UV-blocking Contact Lenses," Faubl, H., International Contact Lens Clinic, Vol. 25, no. 5, 1998.

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 eye care professional for more information.

INDICATIONS

- Precision UV contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic or hyperopic and may have 2.00 diopters (D) or less of corneal astigmatism that does not interfere with visual acuity.
- The contact lenses may be prescribed for either daily wear or extended wear from 1 to 7 days between removal for cleaning and disinfecting or disposal, as recommended by the eye care professional. The eye care professional may prescribe the contact lens for either single use disposable wear or for frequent replacement wear, with cleaning, disinfecting and scheduled replacement. When prescribing for frequent replacement wear, the contact lens may be disinfected using a chemical, heat or hydrogen peroxide disinfecting system. Precision UV lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE Precision UV contact lenses when any of the following conditions exist:

- Acute or subacute inflammation of the anterior segment of the eye.
- Any eye disease which affects the cornea or conjunctiva.
- Any active corneal infection: pus (purulent), bacterial, fungal or viral infection.
- Insufficiency of lacrimal secretion.
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease or allergy which may affect the eye or be exaggerated by wearing contact lenses.
- Allergy to any ingredient, such as mercury or thimerosal, in the solutions necessary for care of the lenses.
- Use of any medication that contraindicates contact lens wear.
- Patient is unable to follow lens care regimen or unable to obtain assistance.
- If eyes become red or irritated.

WARNINGS

- PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. Therefore, after a thorough eye examination, including appropriate medical background, patients must be carefully appraised by the prescribing professional of all the risks associated with contact lens wear. To minimize these risks, the need for strict compliance with the lens care regimen including cleaning of the contact lens storage case is necessary.
- Since eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision, it is important that patients be instructed in the possible signs or symptoms of problems and the need to remove the contact lenses and be examined by the prescribing eye care professional or a corneal specialist immediately if they experience any symptoms such as those listed below under ADVERSE REACTIONS.
- The risk of ulcerative keratitis has been shown to be greater among users of extended wear lenses than among users of daily wear lenses. The risk among extended wear lens users increases with the number of consecutive days that lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning of the lens storage case. Additionally, smoking increases the risk of ulcerative keratitis for contact lens wearers.

- It is recommended that contact lens wearers see their eye care professional twice each year, or as recommended by the eye care professional.

PRECAUTIONS

When prescribing contact lenses, all PRECAUTIONS should be carefully observed. It is strongly recommended that the professional review the appropriate patient instructions with the patient to be sure the patient understands all instructions for their wearing schedule prior to dispensing the contact lenses.

For a disposable wearing schedule: Precision UV contact lenses are intended to be disposed of once they are removed from the patient's eye. Therefore, it is important that patients be instructed to always have a pair of new, sterile replacement contact lenses available. In the event that a contact lens must be removed from the eye because dust, a foreign body or other contaminant adheres to the contact lens, or the contact lens becomes dehydrated, the contact lens should be removed from the eye and replaced with a new, sterile replacement contact lens. If replacement lenses are not available, the patient should refer to the Emergency Contact Lens Care Directions in the Patient Instruction booklet.

For a frequent replacement wearing schedule: in the event that a contact lens must be removed from the eye because dust, a foreign body or other contaminant adheres to the contact lens, the contact lens should be cleaned and disinfected before reapplication to the eye. If the contact lens becomes dehydrated, follow the contact lens care directions for CARE FOR A DEHYDRATED CONTACT LENS.

Ensure the patient understands the following contact lens care precautions:

- Before leaving the eye care professional's office, the patient should demonstrate the ability to properly apply and remove the contact lenses.
- 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.
- Do not touch contact lenses with the 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.
- Never wear lenses beyond the period recommended by the eye care professional.
- The contact lens must move freely on the eye for the continued good health of the eye. The patient should be instructed to follow the directions for CARE FOR A STICKING LENS if they experience non-movement of the contact lens.
- The patient should be instructed against the use of tweezers or other tools to remove contact lenses from the blister pack or lens storage case. The patient should never touch the contact lens with his or her fingernails.
- Instruct the patient to always use a recommended lens care system to care for Precision UV contact lenses and carefully follow all label directions.
- Instruct the patient to always use FRESH rinsing and storing solutions; never reuse solutions.
- Caution the patient in a frequent replacement wearing schedule or in an emergency disposable situation against alternating thermal (heat) and chemical (not heat) lens care systems unless indicated in the lens care system labeling; chemical disinfecting solutions should not be used with heat unless the product labeling indicates the use of both chemical and heat.
- Caution the patient against using conventional hard contact lens solutions that are not also recommended for use with soft hydrophilic lenses.
- Advise the patient to always empty and rinse the contact lens storage case with fresh, sterile rinsing solution and allow it to air dry when not in use. Contact lens storage cases are a source of contamination that can lead to serious eye injury.
- Instruct the patient to always keep the contact lenses completely immersed in the recommended storage solution when the lenses are not being worn to avoid dehydration. If the lenses become dehydrated, the patient should follow the lens care directions for CARE FOR A DEHYDRATED CONTACT LENS.
- The patient should be instructed to avoid using aerosol products such as hair spray while wearing contact lenses. If sprays are used, eyes should be kept closed until the spray has settled.
- The patient should be instructed to inform their employer that contact lenses are worn, as some jobs may require the use of eye protection equipment or that contact lenses not be worn.
- The patient should be instructed to inform their physician that contact lenses are worn and to consult the eye care professional before using any medication in the eye.
- Fluorescein sodium should not be used while contact lenses are on the patient's eye. The lenses may absorb this dye and become discolored. When fluorescein is used, the patient's eyes should be thoroughly flushed with a sterile saline solution recommended for in-eye use. The patient should be advised to wait at least one hour before reapplying their contact lenses.
- Always discard disposable lenses and lenses worn on a frequent replacement schedule after the recommended wearing schedule prescribed by the eye care professional.

ADVERSE REACTIONS

The following problems may occur when wearing contact lenses:

- Eyes sting, burn or itch (irritation)
- Comfort is less than when the contact lens was first placed on the eye
- Feeling of something in the eye (foreign body), scratched area
- Excessive 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 experiences any of the adverse reactions listed above, they should be instructed to follow the appropriate procedure outlined below:

Disposable Wearing Schedule:

- Immediately remove the contact lens from the eye.
- If the discomfort or problem stops, discard the lens and replace it with a new, sterile replacement contact lens.
- If the discomfort or problem persists, discard the lens and IMMEDIATELY consult the eye care professional. DO NOT place any contact lens on the affected eye until instructed to do so by the eye care professional.

Frequent Replacement Wearing Schedule:

- Immediately remove the contact lens from the eye.
- If the discomfort or problem stops, carefully examine the contact lens for damage and/or debris. If the lens appears damaged, discard the lens and replace it with a new, sterile replacement contact lens. If the contact lens appears undamaged but has dirt, an eyelash or other foreign body on it, thoroughly clean, rinse and disinfect the lens; then reapply it to the eye.
- If the discomfort or problem persists, DO NOT put the contact lens back on the eye. Store it in the recommended storage solution and IMMEDIATELY consult the eye care professional. DO NOT place any contact lens on the affected eye until instructed to do so by the eye care professional.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to keep lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

ADVERSE EFFECT REPORTING

If a patient experiences any adverse effects associated with the use of Precision UV lenses, eye care professionals please notify: CIBA Vision Corporation, Technical Consultation, 1-800-241-7468.

FITTING

Conventional methods of fitting soft contact lenses apply to Precision UV contact lenses. For a detailed description of the fitting technique refer to the Precision UV contact lens Professional Fitting Guide. Copies are available from:

CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia 30097

LENS REPLACEMENT SCHEDULE

For frequent replacement wear, the contact lens wearing time recommended is for 2 weeks to 1 month. Each time the contact lens is removed before the replacement time has elapsed, the contact lens must be both cleaned and disinfected prior to placing it back on the eye. The eye care practitioner should determine the wearing schedule based on the response of the patient.

WEARING SCHEDULE

THE WEARING SCHEDULE SHOULD BE DETERMINED BY THE EYE CARE PROFESSIONAL. The contact lens professional may prescribe the contact lens for either single use disposable wear in an extended wear mode or for frequent replacement wear with cleaning, disinfecting and scheduled replacement. When prescribing for frequent replacement wear, the contact lens may be disinfected using a chemical or hydrogen peroxide disinfecting system.

Daily Wear:

There may be a tendency for the daily wear patient to overwear the contact lenses initially. Therefore, the importance of adhering to the proper, initial daily wearing schedule should be stressed to these patients. The wearing schedule should be determined by the eye care professional. The wearing schedule chosen by the eye care professional should be provided to the patient. These contact lenses may be worn on a frequent replacement wearing schedule.

Extended Wear:

The wearing schedule should be determined by the prescribing eye care professional for each individual patient, based upon a full ocular examination and patient history as well as the professional's experience and professional judgement. The wearing schedule chosen by the eye care professional should be provided to the patient. CIBA Vision recommends beginning extended wear patients with the recommended 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 professional should examine the patient in the early stages of extended wear in order to determine corneal response to extended wear. To facilitate proper examination, the lens must first be removed from the eye. Once removed, a lens should remain off the eye for a period of rest overnight or longer, as determined by the

prescribing eye care professional. The lens must be cleaned and disinfected prior to reapplication to the eye or disposed of and replaced with a new, sterile replacement contact lens.

Clinical studies have shown that Precision UV contact lenses are safe to wear during sleep.

CAUTION: Not every patient is able to wear Precision UV contact lenses on an extended wear basis, even if the same patient can wear the contact lens on a daily wear basis. The eye care professional will determine the wearing schedule that is best for the patient.

Clinical studies have shown that wearers' eyes adopt readily to wearing Precision UV contact lenses on an extended wear basis.

With extended wear, there may be increased risks of eye problems such as irritation, infection, corneal thickening and corneal ulcers; therefore, regular checkups, as determined by the eye care professional, are extremely important to assure continued ocular health.

LENS CARE DIRECTIONS

BASIC INSTRUCTIONS

- When dispensing contact lenses, the eye care professional should provide the patient with appropriate and adequate instructions and warnings for proper contact lens care and handling. The eye care professional should recommend procedures and products for each patient in accordance with the particular contact lens wearing schedule and care system selected by the professional. For disposable wear, the contact lenses should only be cleaned and disinfected on an emergency basis following the procedure for Emergency Contact Lens Care in the Patient Instruction booklet, when replacement lenses are not available. The professional should always recommend the patient use contact lens care products intended for use with soft (hydrophilic) contact lenses.

CLEANING FOR FREQUENT REPLACEMENT WEAR

Precision UV contact lenses must be cleaned and disinfected each time they are removed from eyes.

- After removing the lenses and prior to disinfecting them, clean the lenses. Apply several drops of a recommended cleaning solution and rub the lens between your thumb and forefinger for approximately ten seconds for each lens. Or, you may place the lens on the palm of your hand and rub it with the index finger; then turn it over and clean the other side in the same manner.
- After cleaning, rinse each lens thoroughly with a sterile saline solution.

CHEMICAL (NOT HEAT) LENS DISINFECTION

To chemically disinfect your lenses, follow these steps carefully:

- After cleaning and thoroughly rinsing the lenses, prepare the empty lens storage case.
- Wet the lens chambers (sections) with a disinfecting solution.
- Place the lenses into the correct chambers.
- Fill the chambers with disinfecting solution. Completely cover the lenses.
- Tightly close the top of each chamber of the lens storage case.
- To disinfect the lenses, leave them in the solution for the time recommended by the manufacturer.

NOTE: DO NOT HEAT THE DISINFECTING SOLUTION AND LENSES.

- Leave the lenses in the unopened storage case until ready to put on the eye.
- Thoroughly RINSE the lenses with fresh rinsing or disinfecting solution before inserting and wearing.

HYDROGEN PEROXIDE LENS DISINFECTION

To disinfect lenses using a hydrogen peroxide system follow the instructions provided with your recommended lens care system.

WARNINGS: Never place hydrogen peroxide solution directly into the eye. DO NOT USE THERMAL DISINFECTION FOR LENSES WHICH HAVE BEEN CHEMICALLY TREATED. They may be damaged and, if worn after boiling, may cause eye irritation.

NOTE: If other lens care products are used, follow the instructions provided with each product.

After reinserting your lens, always empty the lens storage case, rinse with fresh rinsing solution and allow to air dry. When you next use the lens storage case, refill it with fresh storage solution.

CARE FOR A DEHYDRATED CONTACT LENS

If the Precision UV contact lens is off the eye and exposed to air for 30 minutes or longer, it will become dry and brittle. Patients should be instructed to follow the appropriate procedure outlined below if their contact lens becomes dehydrated:

Disposable Wearing Schedule: Dehydrated contact lenses should be disposed of. Therefore, the patient should always have a pair of new, sterile replacement contact lenses available for use.

Frequent Replacement Wearing Schedule:

- Handle the lens carefully.
- Place the dehydrated contact lens in the storage case and SOAK for at least two hours in a recommended rinsing and storage solution. Soak the lens until it returns to a soft state.
- If after soaking the contact lens does not become soft, DO NOT USE THE LENS, but contact the eye care professional.
- If the contact lens returns to a soft state after soaking and appears undamaged, clean and disinfect the rehydrated contact lens using the lens care system recommended by the eye care professional.

CARE FOR A STICKING LENS

If the lens sticks (stops moving) on the eye, apply 2-3 drops of the recommended sterile rewetting or lubricating solution. Wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues, immediately consult the eye care professional.

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 CONTACT THE EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

Each sterile lens is supplied in a foil-sealed package containing phosphate buffered saline solution. The plastic package is marked with the lens power, expiration date, base curve/diameter identification and manufacturing lot number.

ADDITIONAL INFORMATION

For answers to your questions about the Precision UV (vasurfilcon A) soft (hydrophilic) contact lenses, contact our Professional Consultation Services at 1-800-241-7468 during regular business hours.

For additional copies of the Eye Care Professional's Booklet Insert, Fitting Guide and Patient Instruction Manuals, contact our Customer Service Department at 1-800-241-5999.

PAT. PROTECTED

US No.: 4,955,580; 5,114,629
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