

**IMPORTANT:** This package insert is effective as of July 2001 and supersedes all prior inserts for the product described below. Please read carefully and keep this information for future use. This package insert is intended for the eyecare professional, but should be made available to patients upon request. In the U.S.A copies of this Package Insert are available without charge from CIBA Vision Corporation by calling CIBA Vision Customer Service in the USA at 1-800-241-5999, in Canada at 1-800-268-3968 or copy from our website at [www.cibavision.com](http://www.cibavision.com). The eye care professional should provide the patient with appropriate instructions that pertain to the patient's prescribed lens. CIBA Vision makes available a Patient Instruction Booklet which is recommended to be given to the patient.

**Rx Only**

**CAUTION:** FEDERAL LAW (USA) PROHIBITS DISPENSING WITHOUT A PRESCRIPTION

**DESCRIPTION**

The Choice A.B.™ (methafilcon A) Soft (Hydrophilic) Contact Lens is available as a single vision lens.

**LENS MATERIAL**

The lens material (methafilcon A) is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid cross-linked with ethyleneglycol dimethacrylate (45%) and water (55%). Choice A.B.™ (methafilcon A) Soft Contact Lenses are tinted using the following color additive: Reactive Blue 19

Choice A.B.™ (methafilcon A) Soft Contact Lenses are hemispherical flexible shells which cover the cornea and a portion of the adjacent sclera with the following dimensions:

**LENS PROPERTIES**

- Chord Diameter: 14.0mm to 15.0mm
- Center Thickness: 0.06mm to 0.40mm
- Base Curve: 8.40mm to 9.30mm
- Powers: -20.00 Diopters to +20.00 Diopters

The physical/optical properties of the lens are:

- Refractive Index: 1.42
- Light Transmittance : Approximately 98%
- Surface Character: hydrophilic
- Water Content: 55%
- Specific Gravity: 1.06
- Oxygen Permeability (Dk):  $18.8 \times 10^{-11}$  (cm<sup>2</sup> /sec) (ml O<sub>2</sub> /ml x mm Hg) at 35°C [Fatt Method for determination of oxygen permeability]
- Tint: Light Blue Handling Tint

**ACTIONS**

- When hydrated and placed on the cornea, Choice A.B.™ (methafilcon A) Soft Contact Lenses act as refracting media to focus light rays on the retina. Choice A.B.™ Lenses are tinted for visibility purposes from edge to edge and have a visible light transmittance of approximately 98%.

**INDICATIONS (USES)**

- The Choice A.B.™ (methafilcon A) Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 Diopters that does not interfere with visual acuity.
- Eye care professionals may prescribe the lens for daily wear in a Frequent Replacement Program (see **Lens Replacement** for a description of the wearing schedule). The lenses may be disinfected using chemical or hydrogen peroxide disinfection systems.

**CONTRAINDICATIONS (REASONS NOT TO USE)**

DO NOT USE Choice A.B.™ (methafilcon A) Soft Contact Lenses when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Insufficiency of lacrimal secretion (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 which is to be used to care for the lens
- Any active corneal infection (bacterial, fungal, or viral)
- If the 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 patients follow their eye care professional's directions and all labeling instructions for proper use of lenses and lens care products, including the lens case.
- **EYE PROBLEMS, INCLUDING CORNEAL ULCERS CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION.** The risk of ulcerative keratitis has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses. The risk increases with the number of consecutive days that the lenses are worn between removals, even with the first overnight use<sup>1</sup>.
- **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<sup>2</sup>.** If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove the lenses and promptly contact his or her eye care professional.

**PRECAUTIONS**

**Special Precautions to the Eye Care Professional:**

Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care professional 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 professional.

- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use; and the patient should wait at least 1 hour before replacing the lenses.
- Before leaving the eye care professional'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.

**Eye care professionals 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.
- Never use solutions recommended for conventional hard contact lenses only.
- Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection.
- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts for the use of contact lens solutions.
- 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 (stored). Prolonged periods of drying may damage the lenses. Follow the lens care directions for CARE FOR A DRIED OUT (DEHYDRATED) LENS if lens surface does become 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 non-movement of the lens continues, the patient should be instructed to immediately consult his or her eye care professional.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorant, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- 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.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for the Choice A.B.™ (methafilcon A) Soft Contact Lenses and those prescribed by the eye care professional.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can discolor the lenses.
- Never wear lenses beyond the period recommended by the eye care professional.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eyecare professional about wearing lenses during water activities and other sports.
- 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 eye care professional 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.
- When Choice A.B.™ (methafilcon A) Soft Contact Lenses are prescribed in a Frequent Replacement Program they are intended to be disposed of at the end of the prescribed period (every two weeks). Therefore, it is important to always have available a pair of replacement lenses.

**ADVERSE EFFECTS:**

The patient should be informed that the following problems may occur:

- Eye pain
- Eyes sting, burn, or itch (irritation)
- Comfort is less than when lens was first placed on eye
- Abnormal feeling of something in the eye (foreign body, 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 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 the eye. Place the lens in the storage case and contact the eye care professional. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, the patient should IMMEDIATELY remove the lenses and consult 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.

#### FITTING

Conventional methods of fitting soft contact lenses apply to the **Choice A.B.™ (methafilcon A) Soft (Hydrophilic) Soft Contact Lenses**. For a detailed description of the fitting techniques, refer to the **Choice A.B.™ (methafilcon A) Soft Contact Lenses Fitting and Information Guide**, copies of which are available free of charge from:  
CIBA Vision Corporation  
11460 Johns Creek Parkway, Duluth, Georgia 30097

#### WEARING SCHEDULE

##### THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PROFESSIONAL.

Patients tend to overwear the lenses initially. The eye care professional should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eye care professional, are also extremely important.

##### • DAILY WEAR (less than 24 hours, while awake)

- The maximum daily wearing time should be determined by the eye care professional based upon the patient's physiological eye condition because individual responses to contact lenses vary. Patients tend to overwear the lenses initially. The eye care professional should stress the importance of adhering to the initial maximum wear schedule. Studies have not been conducted to show that **Choice A.B.™** lenses are safe to wear during sleep, therefore patients should be advised to remove their lenses while sleeping. Normal daily wear of lenses assumes a minimum of 6 hours of non-lens wear per 24 hour period. Optimum individual wearing schedules will vary.

**Choice A.B.™ (methafilcon A) Soft Contact Lenses** are indicated for daily wear. The maximum suggested wearing time for the lenses is:

Day	Hours
1	4
2	5
3	6
4	7
5	8
6	9
7	10
8	11
9	12
10 and after-	all waking hours

#### LENS CARE DIRECTIONS

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

**General Lens Care:** First 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. Never re-use solution.
- Use the recommended system of lens care, either chemical (not heat) or oxidation (hydrogen peroxide) 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.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the 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, and disinfect lenses according to the schedule prescribed by the eye care professional. The use of an enzyme or any cleaning solution does not substitute for disinfecting.

- The eye care professional should recommend a care system that is appropriate for the **Choice A.B.™** (methafilcon A) Soft Contact Lenses. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

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 instructions.

##### Chemical Disinfecting Method:

- Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, disinfect lenses using the system recommended by the manufacturer and/or the eye care professional.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. Lenses stored longer than 12 hours may require cleaning, rinsing and disinfecting again before use. The patient should consult the package insert or the eye care professional for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as 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/storage solution. Replace lens case at regular intervals.
- Do not heat the disinfecting solution and lenses.

##### Hydrogen Peroxide Disinfecting Method:

- Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline or neutralizing solution to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, disinfect lenses using the system recommended by the manufacturer and/or the eye care professional.
- When using hydrogen peroxide lens care systems, lenses must be neutralized before wearing. Follow the recommendations on the hydrogen peroxide system labeling.
- Thoroughly rinse lenses with fresh saline or neutralizing solution before inserting and wearing, or follow the instructions on the hydrogen peroxide system labeling.
- Do not heat the hydrogen peroxide solution and lenses.
- Leave the lenses in the unopened storage case until ready to put on the eyes.

**Caution:** Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement on the eye should reduce the potential for irritation.

#### LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE

Enzyme cleaning may be recommended by the eye care professional. 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 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 the eye care professional.

#### CARE FOR A DRIED OUT (DEHYDRATED) LENS

If a **Choice A.B.™** (methafilcon A) Soft Contact Lens is off of the eye and exposed to air for twenty minutes or longer, it will become dry and brittle. To rewet the lens:

- Place the lens in its storage case and soak the lens in recommended rinsing and storage solution for at least one hour or until the lens again feels soft and pliable.

- Clean, rinse and disinfect the rewetted lens using the lens care system recommended by the eye care practitioner.
- If after soaking, the lens does not become soft or the surface remains dry, **DO NOT PLACE THE LENS IN THE EYE**. Contact the eye care professional.

#### CARE FOR A STICKING LENS

If the lens sticks (stops moving), the patient should be instructed to apply 1 to 2 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 nonmovement of the lens continues after 5 minutes, the patient should 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 blister pack containing carbonate buffered saline solution. Hands should be thoroughly washed and rinsed and dried with a lint free towel prior to handling a lens. In order to insure sterility, the blister pack 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.

#### FREQUENT REPLACEMENT PROGRAM

For complete information concerning the Frequent Replacement Program, please refer to the Professional Fitting and Information Guide for **Choice A.B.™ (methafilcon A) Soft Contact Lenses**. CIBA Vision recommends lens replacement every two weeks.

#### 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 patients should: **FLUSH EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVE LENSES PROMPTLY. CONTACT THE EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

#### HOW SUPPLIED

Each lens is supplied sterile in blister packs containing carbonate buffered saline solution. The blister pack is labeled with the base curve, diopter power, diameter, lot number, and expiration date of the product.

#### REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing **Choice A.B.™ (methafilcon A) Soft Contact Lenses** should be reported to:  
CIBA Vision Corporation: 1-800-241-7468



Manufactured for:  
US Corporate Offices:  
CIBA Vision Corporation  
11460 Johns Creek Parkway  
Duluth, Georgia USA 30097

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<sup>1</sup>The CLAO Journal, January 1996, Volume 22, Number 1, pp. 30-37.

<sup>2</sup>New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783.