PROFESSIONAL FITTING GUIDE

IMPORTANT: Please read carefully and keep this information for future use.

This fitting guide is intended for the eyecare practitioner, but should be made available to the patient upon request. The eyecare practitioner should provide the patient with the wearer's guide that pertains to the patients prescribed lens.

Encore A (METHAFILCON A) and OMEGA 56 (ETAFILCON A)
DAILY WEAR SOFT CONTACT LENS

AND

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

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INTRODUCTION:

The **Encore A (Methafilcon A) Soft (hydrophilic) Contact Lens** is made from Methafilcon A with a water content of 55% and the **OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens** is made from Etafilcon A with a water contact of 42%.

This Professional Fitting Guide has been developed to provide practitioners with information covering characteristics of the **Encore A (Methafilcon A) and OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens** to illustrate fitting procedures. It is effective as of October, 1998. Please read carefully and keep this information for future use.

PRODUCT DESCRIPTION:

The **Encore A (Methafilcon A) Soft (hydrophilic) Contact Lens** is a hydrophilic polymer of 2-hydroxyethl methacrylate (HEMA) and methacrylic acid cross-lined with ethyleneglycol dimethacrylate (45.0%) ad water (55.0%).

The **OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens** is a co-polymer of HEMA and methacrylic acid cross-linked with trimethylolpropane trimethacrylate and ethylene glycol dimethacrylate and 58% water. It consists of UV Blocker; a Benzophenone UV absorbing monomer that used to block UV radiation. The UV blocking for averages > 99% in the UVB range of 280nm - 315nm and 83% in the UVA range of 316 - 380nm.

The **Encore A (Methafilcon A) and OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens** are tinted using the color addictive: Reactive Blue 19.

DESIGN: The **Encore A (Methafilcon A) and OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens** are available as a single vision lens and are hemispherical flexible shell which covers the cornea and a portion of the adjacent sclera.

The physical/optical properties of the **Encore A (Methafilcon A)** are:

Refractive Index (wet)	:	1.42
Light Transmittance	:	Approximately 98%
Surface Character	:	Hydrophilic
Water Content	:	55%
Oxygen Permeability (Dk)*	:	18.8×10^{-11} (cm^2 /sec) (ml O_2 /ml x mmHg) @ 35^oC

The physical/optical properties of the **OMEGA 56 (Etafilcon A)** are:

Refractive Index (wet)	:	1.4050
Light Transmittance	:	greater than 91%
Surface Character	:	Hydrophilic
Water Content	:	58 %
Oxygen Permeability (Dk)*	:	21.83 x 10^{-11} (cm^2 /sec) (ml O_2 /ml x mmHg) @ 35°C

*[Fatt Method for determination of oxygen permeability]

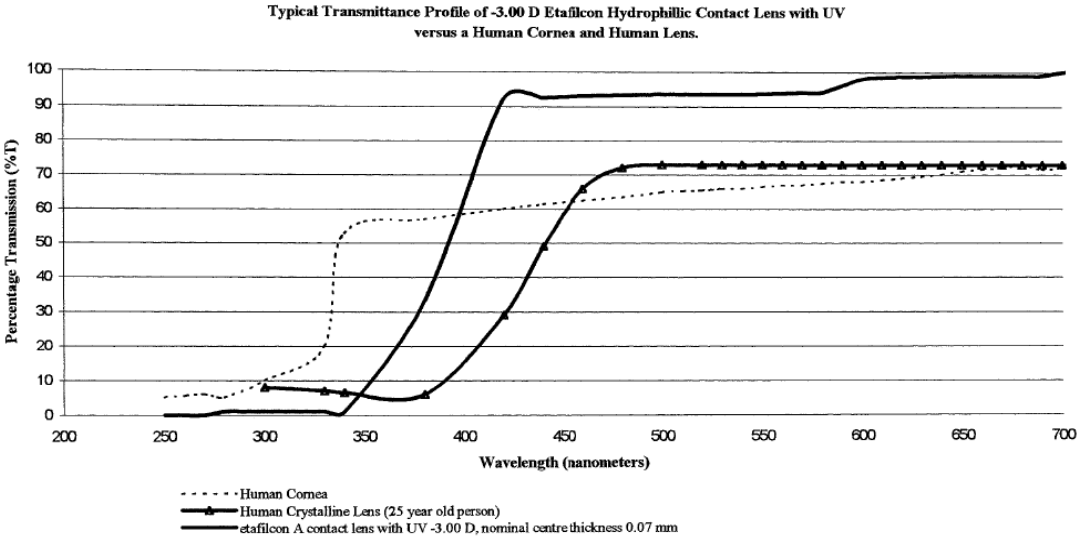
LENS PARAMETER AVAILABLE:

Powers	:	-20.00 to +20.00D
Center Thickness	:	0.06 to 0.40mm
Diameter	:	14.0 to 15.0mm
Base Curve (Encore A)	:	8.40 to 9.30mm
Base Curve (OMEGA 56)	:	8.00 to 9.80mm

WARNING:

UV-absorbing contact lenses are not substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses. Persons should continue to use their protective UV-absorbing eyewear as directed.

The following graph compares the W transmittance curve of the **OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens** , -3.00 D to that of the human cornea of a 24 year old person and that of the human crystalline lens from a 24-year-old. Person as described in Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p.58. **Crystalline Lens –** 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.



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 eyecare practitioner for more information.

See Package Insert for *INDICATIONS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS* AND *ADVERSE EFFECTS*.

INTENDED USE:

The **Encore A (Methafilcon A) Soft (hydrophilic) Contact Lens** is intended for daily wear for the correction (except for plano lenses) 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.

The **OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens** is indicated for daily wear for the correction of visual acuity (except for plano lenses) in aphakic and not aphakic persons with non-diseased eyes with myopia and hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 0.75 Diopters or less where the astigmatism does not interfere with visual acuity.

The lenses may be disinfected using a chemical or hydrogen peroxide disinfection system. Eyecare practitioners may prescribe for lenses for daily wear and/or frequent replacement. When prescribed for a Frequent Replacement Program, the lenses may be disinfected using chemical or hydrogen peroxide disinfection systems.

ACTIONS:

In its hydrated state, the **Encore A (Methafilcon A) and OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens** when placed on the cornea act as refracting media to focus light rays on the retina. The near portion of the aspheric design places the incoming light rays on the retina when viewing reading material at the reading distance.

PATIENT SELECTION:

- **Encore A (Methafilcon A) Soft (hydrophilic) Contact Lens** is intended for patients that requires optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.
- **OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens** is intended for patients that requires for the correction of visual acuity (except for plano lenses) in aphakic and not aphakic persons with non-diseased eyes with myopia and hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 0.75 Diopters or less of astigmatism.
- The lenses are also intended for patients, whom have undergone treatment of acute or chronic ocular pathologies such as, bullous keratopathy, corneal erosions, entropion, corneal edema, and corneal dystrophies as well as post surgical conditions resulting from cataract extraction an corneal surgery, to be used as a therapeutic bandage to relieve corneal pain, at the sole discretion and under direct supervision of a qualified and licensed eyecare professional.
- With the cosmetic effects, such as tints, under the sole discretion and direct supervision of a qualified eyecare professional, the lenses are also intended for use as prosthetic devices for sighted and non-sighted eyes, with or without lens power.
- Persons who require only visual correction and who would not or could not adhere to a recommended care regimen of the **Encore A (Methafilcon A) and OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens** or are unable to place and remove the lenses should not be provided with them. Failure to follow handling and wearing instructions could lead to serious eye infections, which might result in corneal ulcers.
- Patient communication is vital because it relates not only to patient selection, but also to ensuring patient compliance. It is also necessary to discuss the information contained in the Patient Instruction/ Wearer's Guide with the patient at the time of the initial examination.
- Patients selected to wear **Encore A (Methafilcon A) or OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens** should be chosen for their motivation to wear contact lenses, general health and cooperation. The eyecare practitioner must take care in selecting, examining and instructing patients. Patient hygiene and willingness to follow practitioner instructions are essential to their success.
- A detailed history is crucial to determining patient needs and expectations. Your patient should be questioned regarding vocation, desired lens wearing time (full or part time) and desired lens usage (reading, recreation or hobbies).

- Initial evaluation of the trial lens should be preceded by a complete eye examination, including visual acuity with and without correction at both distance and near, keratometry and slit lamp examination.

***FITTING PROCEDURE for the* Encore A (METHAFILCON A) AND OMEGA 56 (ETAFILCON A) SOFT (HYDROPHILIC) CONTACT LENS**

1. Perform a preliminary evaluation to determine distance refraction as well as to rule out contraindications to contact lens wear as described in the Package Insert.
2. Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane.
3. Place on the eye. Allow the lens to remain on the eye long enough to achieve a state of equilibrium. Small variation in the tonicity, pH or the lens solutions and individual tear composition may cause slight changes in fitting characteristics.
4. If the initial lens selection covers the patient's cornea fully, provides discernible movement (0.10mm to 0.30mm) after blink, is comfortable for the patient and provides satisfactory visual performance, it is a well fitted lens and can be dispensed. (See ***Criteria for a Well-fitted Lens*** for **CLINICAL ASSESSMENT**).
5. Full coverage of the cornea is defined as the lens edge extending beyond the limbal area in all directions. Initial lens evaluation must be done after at least 10 minutes of lens wear to allow the lens to stabilize and any tearing to subside.
6. Following a blink, the lens should move vertically on the patient's eye about 0.10mm to 0.30mm. Using a slit lamp, this movement can be estimated by comparing it with the one millimeter lens peripheral bevel width.
7. When lenses are dispensed for vision correction, the wearer must be supplied with an appropriate wearing regimen and must fully understand all lens handling and emergency lens care instructions to prevent lens damage as described in the Package Insert and Patient Instruction/ Wearer's Guide.

IN OFFICE CARE OF TRIAL LENSES:

Trial lenses should be cleaned, rinsed and disinfected after each use following recommended care instructions with any of the chemical or hydrogen peroxide lens care system approved for use with soft contact lenses. Storage of trial lenses which have been reconditioned should be subject to re-disinfection procedures on a periodic basis; at least weekly.

WEARING SCHEDULE

The wearing schedule should be determined by the prescribing eyecare practitioner for each individual patient, based upon a full examination and patient history as well as the practitioner's experience and professional judgment. Patients should be given a wearing schedule and carefully instructed on the handling and care of their lenses as discussed in

the Package Insert. Also be sure to complete the personal wearing/replacement schedule record in the Patient Instruction/ Wearer's Guide. The lens must be removed, cleaned, disinfected or disposed of and replaced with a new lens as determined by the prescribing eyecare practitioner. (See the factors discussed in the WARNINGS section.)

Follow-up examinations are necessary to ensure continued successful contact lens wear and to ascertain the effects of the lenses on the eyes. The following schedule is a suggested guideline for daily wear contact lenses:

- 24 hours post-dispensing
- 7 days
- 1 month
- 3 months
- Every 6 months thereafter

CLINICAL ASSESSMENT:

1. Criteria of a Well-Fitted Lens

   - to 1.0mm movement in primary gaze
   - to 1.5mm movement in upgaze
   - centration in primary gaze

2. Characteristics of a Tight Lens

   - <0.5mm movement in primary or upgaze

3. Characteristics of a Loose Lens

   - >1.0mm movement in primary gaze
   - >1.5mm movement in upgaze
   - poor centration in primary and upgaze

MONOVISION FITTING GUIDELINES

1. Patient Selection

   A. Monovision Needs Assessment

   For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient with significant astigmatism (greater than one diopter) in one eye may not be a good candidate for monovision with **Encore A (Methafilcon A) and OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens**.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis) it should be determined by trial whether this patient can function adequately with monovision. Monovision contact lens wear may not be optimal for such activities as:

i. Visual demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
ii. Driving automobiles (e.g. driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised not to drive with this correction, OR may require that additional over-correction be prescribed.

B. Patient Education

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that monovision, as well as other presbyopic contact lenses, or other alternative, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

2. Eye Selection

Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used.

A. Ocular Preference Determination Methods

Method 1 – Determine which eye is the “sight eye”. Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

Method 2- Determine which eye will accept the added power with the least reduction in vision. Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions bet with the near add lens over the right or left eye.

B. Refractive Error Method

For anisometropic corrections, it is generally best to fit more hyperopic (less myopic) eye for distance and more myopic (less hyperopic) eye for near.

C. Visual Demands Method

Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction correct the eye on that side for near.
Example: A secretary who places copy to the left side of the desk will usually function best with near lens on the left eye.

3. Special Fitting Considerations

Unilateral Lens Correction
There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may require only a distance lens.
Example:
A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 lens on the near eye and the other eye left without a lens.
A presbyopic patient requiring a +1.50 diopter add who is -2.50 diopters myopic in the right and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left corrected for near.

4. Near Add Determination

Always prescribe the lens power for the near eye that provides optima near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

5. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines and base curve selection described earlier in this guide.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near add. With trial lenses of the proper power in place observe the reaction t this mode of correction.

Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. The have the patient look at familiar near objects such as a watch face of fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reactions. Only after these vision tasks are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g. typewritten copy) at first and then graduate to news print and finally smaller type sizes.

After the patient's performance under the above conditions is completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

6. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that patient be passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

7. Other Suggestions

The success of the monovision technique may be further improved by having your patient follow the instructions below.

- Having a third contact lens (distance power) to use when critical distance viewing is needed.
- Having a third contact lens (near power) to use when critical near viewing is needed.
- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.
- Make sure of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions.

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.
- The decision to fit a patient with a monovision correction is most appropriately left to the eyecare practitioner in conjunction with the patient after carefully considering the patient's needs.
- All patients should be supplied with a copy of the Patient Instruction/ Wearer's Guide for **Encore A (Methafilcon A) and OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens**.

FREQUENT REPLACEMENT PROGRAM:

The **Encore A (Methafilcon A) and OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens** frequent replacement schedule are prescribed by the eyecare practitioner. At the end of each day, each lens is to be removed, cleaned, and disinfected in the recommended manner prior to re-insertion. Clean and fresh lenses are more comfortable, and are less likely to irritate gentle tissues around the eyes. The eyecare practitioner will recommend an appropriate lens replacement schedule for each patient. He or she will design he schedule for the patient. It is imperative that the patient follow the direction of the eyecare provider.

LENS CARE DIRECTIONS:

Eyecare practitioners 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 the instructions on solution labeling.
- Different solutions cannot always be used together and not all solutions are safe for use with all lens. 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 eyecare practitioner. The use of enzyme or any cleaning solution does not substitute for disinfecting.
- The eyecare practitioner should recommend a care system that is appropriate for the **Encore A (methafilcon A) or OMEGA 56 (Etafilcon A) Soft (Hydrophilic) Contact Lens**. 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 lens into correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, **disinfect** lens using the system recommended by the manufacturer and/or the eyecare practitioner.
- 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 eyecare practitioner for information on storing lenses.
- After removing the lenses from the lens case, empty and rinse the 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 lens into correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, **disinfect** lens using the system recommended by the manufacturer and/ or the eyecare practitioner.
- When using hydrogen peroxide lens care system, 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.

Precaution: Use only a chemical (not heat) lens care system. Use of heat (thermal) care system can discolor the lenses.

LUBRICATING / REWETTING LENSES ON-EYE:

Eyecare practitioners may recommend a lubricating/re-wetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

Disposable and lenses prescribed in a frequent replacement program should be thrown away after the recommended wearing period prescribed by the eyecare practitioners.

CARE FOR A NON-MOVING LENS:

If the lens stops moving or cannot be moved, the patient should be instructed to apply 1 - 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 non-movement of the lens continues after 5 minutes, the patient should immediately consult the eyecare practitioner.

RECOMMENDED LENS CARE PRODUCTS:

The eyecare practitioner should recommend a care system that is appropriate for the **Encore A (Methafilcon A) or OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens**. Each lens care product contains specific instructions for use and important safety information, which should be read and carefully followed.

EMERGENCIES:

The patient should be informed that if any chemical 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 IMMEDIATELY CONTACT YOUR EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing the **Encore A (Methafilcon A) or OMEGA 56 (Etafilcon A) Soft (hydrophilic) Contact Lens** should be reported to the address below.

Additional Package Insert and Patient Instruction/ Wearer's Guide are available from:

Clearlab SG Pte. Ltd.
139 Joo Seng Road,
Singapore 368362
Tel: +65 6749 1090
Fax: +65 6282 3953
Email: Regulatory@clearlab.com
Website: www.clearlab.com

HOW SUPPLIED:

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

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