

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

This package insert 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.

eyedia® soft55 (METHAFILCON A)
DAILY WEAR SOFT CONTACT LENS



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

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DESCRIPTION:

The **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens** is available as a single vision lens. The lens material (methafilcon A) is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid cross-linked with ethyleneglycol dimethacrylate (45.0%) and water (55.0%). The lens polymer contains an UV absorbing compound. The lenses are tinted using the color additive Reactive Blue #19.

The **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens** is a hemispherical shell which cover the cornea and a portion of the adjacent sclera with the following dimensions:

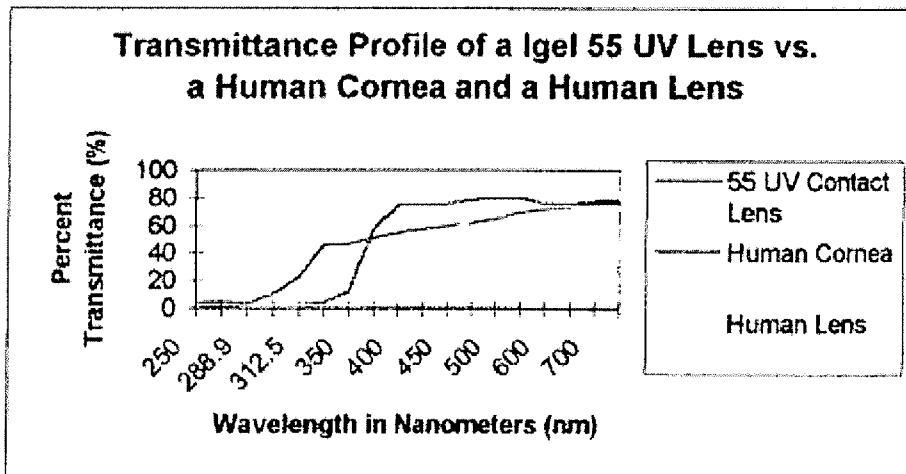
- Chord Diameter : 14.0mm to 15.0mm
- Center Thickness : 0.06mm to 0.40mm
- Base Curve : 8.40mm to 9.30mm
- Powers : -20.00 Diopters to +20.00Diopters

The physical/optical properties of the lens as are:

- Refractive Index : 1.42
- Visible Light Transmittance : 90.3% (Approximately)
- UV Transmittance : <10%
- Surface Character : hydrophilic
- Water Content : 55%
- Specific Gravity : 1.06
- Oxygen Permeability (Dk)* : 18.9×10^{-11} (cm²/sec)(ml O₂/ml x mm Hg) at 35°C
*[revised Fatt Method for determination of oxygen permeability]

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 UV transmittance curve of **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens (-6.50 D)** to that of human cornea of a 24 year old person as described in Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p.58, fig 2-21, and that of the human crystalline lens from a 25 year old, as described in Waxier, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986,



p.19, fig 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 eye care practitioner for more information.

ACTIONS:

In its hydrated state, the **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens**, when placed on the cornea, act as refracting media to focus light rays on the retina when viewing reading material a the reading distance.

INDICATIONS (USES):

The **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

The lens may be disinfected using chemical or hydrogen peroxide disinfecting systems. Eyecare practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement (see WARNING SCHEDULE). When prescribed for a Frequent Replacement Program, the lenses may be disinfected using chemical or hydrogen peroxide disinfecting systems.

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CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the **eyedia[®] soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens** 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.
- Sever insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic.
- 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 **eyedia[®] soft55 (Methafilcon A) Soft (hydrophilic) Contact 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 THE CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN **SERIOUS INJURY TO THE EYE**. It is essential that patients follow their eyecare practitioner's direction 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.**
- 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 non smokers.
- 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 PRACTITIONER.**

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PRECAUTIONS:

Special precautions for Eyecare Practitioners:

- 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 eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the prescribing eyecare practitioner should carefully monitor the continuing ocular health of the patient and lens performance of the eye.

- Patients who wear aspheric contact lenses to correct presbyopia may not achieve the best-corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Aphakic patients should not be fitted with **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens** until the determination is made that the eye has healed completely.
- 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 eyecare practitioner'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.

Eyecare practitioner 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.

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- Always follow directions in the package inserts for the use of contact lens solutions.
- Use only a chemical (not heat) lens care system. Use of the heat (thermal) care system can discolor the **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens**.
- 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 eyecare practitioner.
- 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 Instruction/ Wearer's Guide for the **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens** and those prescribed by the eyecare practitioner.
- Never wear lenses beyond the period recommended by the eyecare practitioner.
- 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 practitioner 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 discard disposable lenses worn on a frequent replacement schedule after the recommended wearing schedule prescribed by the eyecare practitioner.
- Always contact the eyecare practitioner 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.

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- 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.
- The **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens**, when prescribed in a Frequent Replacement Program, is intended to be disposed of at the end of the prescribed period (1 week, 2 weeks, or 1 month). Therefore, it is important to always have available a pair of replacement lenses.

ADVERSE REACTIONS:

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

- Eyes stinging, burning, itching (irritation), or other eye pain.
- 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 LENS.**
- 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 eyecare practitioner. 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 EYECARE PRACTITIONER.**

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 contact lenses apply to the **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens**. For a detailed description of the fitting techniques, refer to the **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens Professional Fitting Guide**, copies of which are available from:

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Clearlab US Inc.

4200 Jenkins Court, Suwanee,
GA 30024, United States of America
Tel: +1 770 2710211
Fax: +1 770 2710225
Email: USRA@clearlab.com
Website: www.clearlabus.com

WEARING SCHEDULE:

THE EYECARE PRACTITIONER SHOULD DETERMINE THE WEARING AND REPLACEMENT SCHEDULES. Patients tend to over wear the lenses initially. The eyecare practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eyecare practitioner, are also extremely important.

The **eyedia[®] soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens** is indicated for daily wear. **THE MAXIMUM SUGGESTED WEARING TIME FOR THE LENSES IS:**

DAY	1	2	3	4	5	6	7	8	9	10 and after
HOURS	4	5	6	7	8	9	10	11	12	All waking hours

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE eyedia[®] soft55 (METHAFILCON A) SOFT (HYDROPHILIC) CONTACT LENS IS SAFE TO WEAR DURING SLEEP.

LENS CARE DIRECTIONS:

Eyecare practitioner 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.

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- 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, enzyme (as recommended by the eyecare practitioner) and disinfect** lenses according to the schedule prescribed by the eyecare practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfecting.
- The eyecare practitioner should recommend a care system that is appropriate for the **eyedia® soft55 (Methafilcon 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.

- **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 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 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 as recommended by the lens case manufacturer or your eyecare practitioner.
- Eyecare practitioners may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.
- **DO NOT HEAT THE DISINFECTING SOLUTION AND LENSES.**

Chemical (Not Heat) Disinfection:

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 eyecare practitioner.

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- 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:

The eyecare practitioner may recommend enzyme cleaning. 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 eyecare practitioner.

Care for a Dried Out (Dehydrated) Dry Lens:

If the **eyedia[®] soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens** is off the eye and exposed to air for twenty minutes or longer, they will become dry and brittle. To rewet:

- 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 eyecare 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 eyecare practitioner.

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Care for a Sticking (Nonmoving) 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 non-movement of the lens continues after 5 minutes, the patient should **IMMEDIATELY** consult the eyecare practitioner.

In Office Care Regimen For Trial Lenses:

Eyecare practitioner should educate contact lens technicians concerning proper care of trial lenses.

Each contact lens is shipped sterile in a blister pack with sterile saline solution. Hands should be thoroughly washed, rinsed and dried with a lint free towel prior to handling a lens. In order to insure sterility, the blister pack should not be opened until immediately prior to use. Lenses surface should be cleaned and disinfected prior to re-using in a diagnostic procedure or before dispensing to a patient.

Follow the disinfection procedures described above for proper disinfection of office trial lenses.

Frequent Replacement Program:

For complete information concerning the Frequent Replacement Program, please refer to the Professional Fitting Guide for the **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens**.

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 EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED:

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

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing the **eyedia® soft55 (Methafilcon A) Soft (hydrophilic) Contact Lens** should be reported to:

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Clearlab US Inc.
4200 Jenkins Court, Suwanee,
GA 30024, United States of America
Tel: +1 770 2710211
Fax: +1 770 2710225
Email: USRA@clearlab.com
Website: www.clearlabus.com

SYMBOLS KEY:

The following symbols may appear on the label or carton.

SYMBOL	DESCRIPTION
	Sterile Using Steam
LOT	Product Lot Number
EXP	Expiry Date
BC	Lens Base Curve
DIA	Lens Diameter
	Caution: Federal law restricts this device to sale by or on the order of a licensed Eye Care Practitioner.
	Caution: This is a single patient use device; See Package Insert or Instructions For Use.
	Lens contains UV blocking properties

CAUTION: Federal law restricts this device to sale by or on the order of a licensed practitioner.

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