

# PACKAGE INSERT: Fluorex® 700, Fluorex® 500 and Fluorex® 300 RGP Contact Lenses

IMPORTANT: PLEASE READ CAREFULLY AND RETAIN FOR FUTURE USE

**DESCRIPTION:** Fluorex 700 (flusilfocon A), Fluorex 500 (flusilfocon B) and Fluorex 300 (flusilfocon C) Rigid Gas Permeable Contact Lenses (hereinafter referred to as Fluorex Contact Lenses) are available in spherical, bifocal, trifocal and toric designs. Each is a shell of the following dimensions.

	Spherical Contact Lens	Bifocal Contact Lens	Trifocal Contact Lens	Toric Contact Lens
Diameter	7.00mm to 10.50mm	8.00mm to 10.50mm	8.00mm to 10.50mm	7.00mm to 10.50mm
Base Curve	6.00mm to 9.00mm	6.50mm to 8.50mm	6.50mm to 8.50mm	6.00mm to 9.00mm
Distance Power	+12.00D to -20.00D	+12.00D to -20.00D	+12.00D to -20.00D	+12.00D to -20.00D
Add Power		+0.75D to +3.50D	+0.75D to +3.50D	
Intermediate Power		+0.50D to +2.50D		
Prism	1.75D to 4.00D	1.75D to 4.00D	1.75D to 4.00D	1.75D to 4.00D
Center Thickness	0.10mm to 1.00mm	0.20mm to 0.80mm	0.20mm to 0.80mm	0.10mm to 1.00mm

**MATERIAL CHARACTERISTICS:** The Fluorex lens materials (flusilfocon A, B and C) are fluoro-silicate-acrylic copolymers available in clear, untinted, aqua, blue, gray, green or rose/brown. The aqua contains D&C Green #6 and CI Solvent Yellow #18. The blue contains D&C Green #6. The gray contains D&C Green #6, D&C Violet #2 and CI Solvent Yellow #18. The green contains D&C Green #6 and D&C Yellow #10. The rose/brown contains D&C Green #6 and D&C Red #17.

The physical properties of the Fluorex Contact Lenses are as follows:

Fluorex® 700	Fluorex® 500	Fluorex® 300
Oxygen Permeability <sup>1</sup>	70.0	Oxygen Permeability <sup>1</sup> 30.0
Wetting Angle <sup>2</sup>	15.3°	Wetting Angle <sup>2</sup> 12.6°
Hardness <sup>3</sup>	85.5	Hardness <sup>3</sup> 87.0
Specific Gravity <sup>4</sup>	1.097	Specific Gravity <sup>4</sup> 1.113
Refractive Index <sup>5</sup>	1.457	Refractive Index <sup>5</sup> 1.465
Water Content <sup>6</sup>	<1%	Water Content <sup>6</sup> <1%
Light Transmission <sup>7</sup>		Light Transmission <sup>7</sup>
Aqua 80.25%, Blue 79.97%, Clear 87.69%, Gray 82.16%, Green 83.44%, R/Brn 87.17%	Aqua 80.31%, Blue 85.25%, Clear 87.69%, Gray 79.84%, Green 80.60%, R/Brn 86.29%	Aqua 81.36%, Blue 77.57%, Clear 88.85%, Gray 83.97%, Green 81.05%, R/Brn 85.04%

1) Determined @35°C by the method of Irving Fatt 2) Determined @35°C by Wilhelmly plate method 3) Determined according to ANZI/ASTM 80.20 paragraph 8.16 4) Determined by picnometry @20°C using distilled water as the reference liquid 5) Determined @20°C according to ANZI/ASTM 80.20 paragraph 8.19 6) Determined by thermogravimetry @110°C 7) Determined @640 nm measured for a lens with a center thickness of 0.10 mm

**ACTION:** The Fluorex Contact Lenses when placed on the cornea act as refracting media to focus light rays onto the retina.

**INDICATIONS:** Fluorex Contact Lenses are indicated for daily wear for the correction of refractive ametropia (astigmatism, hyperopia, myopia and presbyopia) in nonaphakic persons with nondiseased eyes.

**CONTRAINDICATIONS:** DO NOT USE Fluorex Contact Lenses when any of the following conditions exist: • Acute or subacute inflammation between the lens and iris and the cornea or the interior chamber of the eye • Any disease which affects the cornea or conjunctiva • Any active corneal infection: bacterial, fungal or viral • Insufficiency of lacrimal secretion (dry eyes) • Corneal hypesthesia (reduced corneal sensitivity) • Allergy to any ingredient, such as thimerosal, in a solution which must be used to care for the lenses • Any systemic disease which may affect the eye or be exaggerated by wearing contact lenses.

**WARNINGS:** *Problems with contact lenses and contact lens care products could result in serious injury to the eye. It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use of your lenses and lens care products. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. Therefore, if you experience any discomfort, excessive tearing, vision changes or redness of the eye, immediately remove your lenses and promptly contact your eye care practitioner.*

All contact lenses wearers must return for periodic check-up visits as recommended by their care practitioner.

**PRECAUTIONS:** Follow the instructions below to prevent damage to your eyes or your lenses:

- Before you leave your eye care practitioner's office, be able to remove your lenses or have someone else be able to remove your lenses for you.
- Clinical studies have demonstrated that contact lenses manufactured from the flusilfocon lens material are safe and effective for their intended use. However, the clinical studies may not have included all design configurations or lens parameters that are presently available in this lens material. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner must consider all factors that affect lens performance and ocular health. The potential impact of these factors must be weighed against the patient's needs; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored.
- Use only solutions recommended by your eye care practitioner to care for your lenses. The safety of these lenses with medications or contact lens solutions other than those recommended has not been established.
- Always use a lens care system for your Fluorex Contact Lenses that has been recommended for use with fluoro-silicone-acrylate contact lenses.
- Always wash and rinse your hands thoroughly and dry with a lint-free towel before you handle your lenses. Eye irritation may result if cosmetics, lotions, soaps, creams and deodorants come in contact with your lenses or if the lenses come in contact with infectious and/or non-infectious dirt.
- Always use FRESH rinsing and storage solutions.
- Do not use heat or thermal lens care systems. Heat disinfection will damage the lenses.
- Do not use saliva or anything other than the solutions recommended by your eye care practitioner for wetting.
- Always keep the lenses completely immersed in a recommended storage solution when the lenses are not being worn.
- Do not wear Fluorex contact lenses while sleeping.
- Avoid all harmful or irritating vapors and fumes while wearing your lenses.
- Do not swim with your lenses in place.
- Never use tweezers or other tools to remove your lenses from the lens container.
- Do not touch the lenses with your fingernails.
- Avoid using aerosol products such as hair spray while wearing your lenses. If hair spray is used, keep your eyes closed until the spray has settled, otherwise the lenses may be damaged.
- Inform your (doctor) health care practitioner that you wear contact lenses.
- Always consult your eye care practitioner before using any medicine in your eyes.
- Always inform your employer that you wear contact lenses. Some jobs may require that you not wear contact lenses.

If your lens feels dry on the eye or becomes uncomfortable, remove the lens and recondition it with a few drops of a recommended wetting solution. If dryness or discomfort continues, immediately consult your eye care practitioner.

The lens must move freely on the eye for the continued health of the eye. If your lens sticks (stops moving) on the eye, follow the recommended directions on "Care for a Sticking Lens". If non-movement of the lens continues, immediately consult your eye care practitioner.

As with any contact lens, follow-up visits are necessary to assure continued health. Check with your eye care practitioner.

**ADVERSE EFFECTS:** The following problems may occur:

- reduced sharpness of vision (visual acuity)
- feeling of something in the eye (foreign body, scratch area)
- excessive watering (tearing) of the eye
- comfort is less than when lens was first placed on the eyes
- blurred vision, rainbows or halos around objects
- dry eyes
- unusual eye secretions
- eyes sting, burn or itch
- sensitivity to light (photophobia)
- redness of the eyes

If you notice any of these adverse effects immediately remove your contact lenses.

1. If the discomfort or problem stops, then look closely at the lens.
2. If the lens is in any way damaged, DO NOT put it back on your eye. Place the lens in the storage case and contact your eye care practitioner.
3. If the lens has dirt, an eyelash or other foreign body on it or the problem stops and the lens appears undamaged, thoroughly clean, rinse and disinfect the lens with the recommended solutions and then reinsert it.
4. If the problem continues, IMMEDIATELY remove the lens and consult your eye care practitioner.

When any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. Seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

**FITTING INFORMATION:** Conventional methods of fitting rigid contact lenses apply to Fluorex Contact Lenses. For a detailed description of the fitting technique, refer to the Fitting and Information Guide, copies of which are available from G.T. Laboratories, Inc., 2007 Johns Drive, Glenview, Illinois 60025-1616, USA.

**WEARING SCHEDULE:** The wearing schedule should be determined by the eye care practitioner. Patients tend to overwear the lenses initially. It is important to adhere to the initial maximum wearing schedule. Fluorex Contact Lenses are FDA approved for daily wear. The maximum suggested wearing time is as follows:

<u>Day</u>	<u>Hours</u>	<u>Day</u>	<u>Hours</u>
1	4	6	9
2	5	7	10
3	6	8	11
4	7	9	12
5	8	10	all waking hours

**LENS CARE GUIDELINES:** Always wash and rinse your hands before handling your contact lenses. Follow the basic instructions for general lens care to clean, rinse and disinfect your lenses in the Fluorex Patient Care Guide.

- Use only a chemical system recommended for fluoro-silicone-acrylate lens care.
- Never use heat (thermal) lens care systems.
- Your lenses must be BOTH cleaned and disinfected each time you remove them. Cleaning is necessary to remove mucus and film for the surface. Disinfecting is necessary to prevent growth of harmful germs.
- Use only solutions recommended by your eye care practitioner to care for your lenses.

**CLEANING, STORAGE & DISINFECTING PROCEDURES:**

- Clean and rinse one lens first (always the same lens first to avoid mixups) and prepare the empty lens storage case. Wet the lens chamber with a recommended disinfecting solution.
- Put each lens into its correct chamber.
- Fill the chamber with the disinfecting solution. Completely cover the lenses.
- Tightly close the top of each chamber of the lens storage case.

To disinfect your lenses, leave them in the solution for at least four (4) hours or as indicated on the product label. DO NOT HEAT THE DISINFECTING SOLUTION OR THE LENSES.

To store your lenses, disinfect and leave them in the closed/unopened case until ready to wear. If the lenses have been stored in an unopened case for more than 24 hours, disinfect immediately before wearing. Thoroughly rinse your lenses with a recommended rinsing solution before inserting and wearing. After you remove your lens from the lens case, empty and rinse your lens storage case with fresh, hot tap water and allow it to air dry. When you next use the case, refill it with fresh storage solution.

**CARE FOR A STICKING LENS:** If the lens sticks (stops moving) on the eye, apply a few drops of a recommended rinsing or lubricating solution. Wait until the lens begins to move freely on your eye before removing it. If non-movement of the lens continues, immediately consult your eye care practitioner.

**SOLUTIONS:** The following solutions have been used in clinical trials with the flusilfocon material. Your eye care practitioner may recommend alternative lens care products.

**CONTACT LENS CARE SYSTEM:**

<u>Purpose</u>	<u>Brand Name</u>
Clean	Allergan® LC-65® Daily Contact Lens Cleaner
Rinse	Allergan Hydrocare® Preserved Saline Solution
Disinfect/Store	Allergan Hydrocare Cleaning & Disinfecting Solution
Lubricate/Rewet	Allergan Hydrocare Preserved Saline Solution
Enzyme	Allergan Enzymatic Cleaner

\*Allergan, LC-65 and Hydrocare, are registered trademarks of Allergan Pharmaceuticals, Inc., of Irvine, CA.

The package insert accompanying each solution and the package label of each product provide detailed instructions on how the solutions are to be used in caring for contact lenses. Read and follow those instructions carefully. The Fluorex Contact Lenses should only be disinfected by a chemical system of disinfection specifically recommended for use with fluoro-silicone-acrylate lenses.

**HOW SUPPLIED:**

**Caution:** Lenses are supplied non-sterile in a plastic lens storage case. Clean and condition lenses prior to use. The case is labeled with the base curve, dioptric power, diameter, center thickness, color of the lens, lens material lot number and expiration date.

**CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION.**

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