

PATIENT INSTRUCTION GUIDE

FREQUENT REPLACEMENT DAILY WEAR

VISTAKON[®] (galyfilcon A) Contact Lenses

**VISIBILITY TINTED WITH UV BLOCKER
For Daily Wear**

VISTAKON[®]

DIVISION OF
Johnson+Johnson
Vision Care, Inc.

Patient Instruction Guide For Frequent Replacement Daily Wear

VISTAKON® (galyfilcon A) Contact Lenses
VISIBILITY TINTED WITH UV BLOCKER

SYMBOLS KEY

The following symbols may appear on the label or carton:












SYMBOL	DEFINITION
	See Instruction Leaflet
	Use By Date (expiration date)
	Batch Code
	Sterile Using Steam or Dry Heat
DIA	Diameter
BC	Base Curve
D	Diopter (lens power)
	Quality System Certification Symbol
	UV-Blocking
	Fee Paid for Waste Management
	Peel Back Foil
	CAUTION: Federal law restricts this device to sale by or on the order of a licensed practitioner
ACUVUE® ADVANCE™ with HYDRACLEAR™ Lenses	
	Lens Orientation Correct
	Lens Inside Out
ACUVUE® ADVANCE™ for ASTIGMATISM Lenses	
CYL	Cylinder Power
AXIS	Axis

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CAUTION: Federal Law Restricts This Device To Sale By Or On The Order Of A Licensed Practitioner.

INTRODUCTION

Congratulations on choosing the VISTAKON® (galyfilcon A) Contact Lens Visibility Tinted with UV Blocker for Daily Wear Frequent Replacement. A UV-absorbing monomer is used to block UV radiation. When your prescribed replacement period is over, you simply throw the used lens away and replace it with a new sterile one. By replacing your VISTAKON® (galyfilcon A) Contact Lens on a regular basis, there is little chance for long-term build-up, which can affect vision and cause irritation and discomfort to the eye.

The ACUVUE® ADVANCE™ Brand Contact Lenses with HYDRACLEAR™ (galyfilcon A) are soft spherical lenses. The ACUVUE® ADVANCE™ Brand Contact Lenses *for ASTIGMATISM* (galyfilcon A) are soft toric lenses. These VISTAKON® (galyfilcon A) Contact Lenses are made from a “water-loving” (hydrophilic) material that has the ability to absorb water, making the lenses soft and flexible. They differ from other lenses available because of the way they are manufactured. Simply put, the multi-patented manufacturing process, which took years to perfect, makes possible frequent replacement of the VISTAKON® (galyfilcon A) Contact Lens. Since the lenses are produced identically one after another, you will experience the same excellent comfort and vision, lens after lens after lens.

The information and instructions contained in this booklet apply only to the VISTAKON® (galyfilcon A) Contact Lens. The VISTAKON® (galyfilcon A) Contact Lenses are intended to be used for daily wear within the VISTAKON® (galyfilcon A) Contact Lens planned lens replacement system. For your eye health, it is important that the VISTAKON® (galyfilcon A) Contact Lenses be worn as prescribed by your Eye Care Professional. Your Eye Care Professional should be kept fully aware of your medical history. Your Eye Care Professional will tailor a total program of care based on your specific needs. He or she will review with you all instructions for lens handling, including how to safely and easily open the packaging. You will also be instructed on how to properly apply and remove lenses. This booklet will reinforce those instructions. VISTAKON® (galyfilcon A) Contact Lenses should be discarded and replaced with a new sterile pair, as prescribed by your Eye Care Professional. If you have any questions, always ask your Eye Care Professional.

WEARING RESTRICTIONS AND INDICATIONS

The ACUVUE® ADVANCE™ Brand Contact Lens with HYDRACLEAR™ (galyfilcon A) is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased eyes who may have 1.00D of astigmatism or less.

The ACUVUE® ADVANCE™ Brand Contact Lens *for ASTIGMATISM* (galyfilcon A) is indicated for daily wear for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes who are hyperopic or myopic and may have 0.50D to 2.50D of astigmatism.

The VISTAKON® (galyfilcon A) UV-Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.*

The VISTAKON® (galyfilcon A) Contact Lens described in this booklet should be removed from your eyes for routine cleaning and disinfecting as prescribed by your Eye Care Professional. The lens may be disinfected using a chemical disinfection system only. **DO NOT WEAR YOUR VISTAKON® (galyfilcon A) CONTACT LENSES WHILE SLEEPING.**

***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.**

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-blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-blocking contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your Eye Care Professional for more information.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the VISTAKON® (galyfilcon A) 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
- Severe 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 VISTAKON® (galyfilcon A) Contact Lens
- Any active corneal infection (bacterial, fungal, protozoal or viral)
- If eyes become red or irritated

WARNINGS

Problems with contact lenses could result in serious injury to the eye. Proper use and care of contact lenses and lens care products, including lens cases, are essential for the safe use of these products. The following warnings pertain to contact lens wear.

Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. The results of a study¹ indicate the following:

- The overall annual incidence of ulcerative keratitis in daily wear contact lens users is estimated to be about 4.1 per 10,000 persons and about 20.9 per 10,000 persons in extended wear contact lens users.
- The risk of ulcerative keratitis is 4 to 5 times greater for extended wear contact lens users than for daily wear users. When daily wear users who wear their lenses overnight and extended wear users who wear their lenses on a daily basis are excluded from the comparison, the risk among extended wear users is 10 to 15 times greater than among daily wear users.
- When daily wear users wear their lenses overnight (outside the approved indication), the risk of ulcerative keratitis is 9 times greater than among those who do not wear them overnight.

¹ New England Journal of Medicine, September 21, 1989

- The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care, including cleaning the lens case.
- The risk of ulcerative keratitis among contact lens users who smoke is estimated to be 3 to 8 times greater than among non-smokers.

If you experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, you should immediately remove your lenses and promptly contact your Eye Care Professional. It is recommended that you see your Eye Care Professional routinely as directed.

PRECAUTIONS

- **DO NOT** use if the sterile blister package is opened or damaged.
- Patients who wear contact lenses to correct presbyopia using monovision 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.
- Before leaving the Eye Care Professional's office, you should be able to promptly remove the lenses or should have someone else available who can remove the lenses for you.
- You should remove your lenses immediately if your eyes become red or irritated.
- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
 - **DO NOT** use the Ciba Vision® SOLO-care® Plus Multipurpose solution to clean and disinfect the VISTAKON® (galyfilcon A) Contact Lenses because the lens dimensions may become altered.
 - 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 and lenses.
 - 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 heat (thermal) care systems can damage the VISTAKON® (galyfilcon A) 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 your lenses completely immersed in the recommended storage solution when the