CIBA Vision
A Novartis Company

Package Insert for the Focus® Family of (vifilcon A) Soft Contact Lenses, including:
Focus® Monthly Softcolors® and Visitint®, Focus® Monthly Toric Visitint®, and Focus 1-2 Week Softcolors® and Visitint® (formerly NewVues®) and Focus® Progressives Visitint®, (vifilcon A) Soft Contact Lenses When Prescribed for Planned Replacement, Focus® 1-2 Week Softcolors® and Visitint® (formerly NewVues®) and Focus® Progressives Visitint®,(vifilcon A) Soft Contact Lenses When Prescribed for Disposable Wear

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Important: This package insert is effective as of September, 1999 and supersedes all prior inserts for the products described below. Please read carefully and keep this information for future use. This package insert is intended for the eye care professional, but should be made available to patients upon request. The eye care professional should provide the patient with appropriate instructions that pertain to the patient's prescribed lenses. **Copies of this package insert are available without charge from CIBA Vision Corporation by calling CIBA Vision Customer Service at 1-800-241-5999 or download from our website at www.cibavision.com.** CIBA Vision makes available a *Patient Instruction Booklet* which is recommended to be given to the patient.

CAUTION: Federal law (USA) prohibits dispensing without a prescription from a licensed eye care professional.

Product Notes:

- Focus, NewVues, Visitint and Softcolors are registered trademarks of CIBA Vision® Corporation
- In 1998, (vifilcon A) Soft Contact Lenses, formerly marketed as Focus and NewVues, were renamed under the Focus brand, as follows:

Formerly	New
Focus® Visitint®	Focus® Monthly Visitint®
Focus® Softcolors®	Focus® Monthly Softcolors®
Focus® Toric	Focus® Monthly Toric Visitint®
NewVues® Visitint®	Focus® 1-2 Week Visitint®
NewVues® Softcolors®	Focus® 1-2 Week Softcolors®

- Always check for current product availability. Production of clear Focus, NewVues and Focus Toric lenses has been discontinued, while expanded parameters for tinted lenses may be introduced over time.

PRODUCT DESCRIPTION

Lens Material

- The lens material is 55% water and 45% vifilcon A, a hydrophilic co-polymer of 2-hydroxyethyl methacrylate and povidone, USP. The chemical name is poly (2-hydroxyethyl methacrylate-co-ethylene dimethacrylate co-methacrylic acid-g-povidone).
- Visitint and Softcolors lenses are tinted by a patented process. The lens material is modified by permanently fixing tints to the polymer using the following color additives (either alone or in combination): Reactive Blue 21, Reactive Black 5, Reactive Yellow 15, Reactive Orange 78, and Reactive Blue 19.

Lens Properties

- Specific Gravity: 1.12
- Refractive Index (hydrated): 1.415
- Light Transmittance*:

Tint	Transmittance (approx.)
Clear	97%
Visitint	93%
Royal Blue	88%
Aqua	89%
Evergreen	88%

*Note: In conditions of low light, wearers of some darkly tinted contact lenses may experience reduced visibility

- Oxygen Permeability (Dk): 16.0 x 10^{-11} (cm^2/sec)(ml O_2/ml x mm Hg), measured at 23° C (Fatt method)
- Water Content: 55% by weight in normal saline

Available Lens Parameters

Focus 1-2 Week (Visitint and Softcolors, formerly marketed as NewVues)

- Chord Diameter: 14.0 mm
- Center Thickness: 0.06 mm at all minus powers
  0.12 mm at +3.00D (varies with power)
- Base Curves: 8.4 mm and 8.8 mm
- Powers: -6.00D to +4.00D (0.25D steps: Visitint & Softcolors)
  -6.50D to -10.00D (0.50D steps; Visitint only)
- Tints:
  - Visitint: Light blue visibility tint
  - Softcolors: Royal Blue, Aqua and Evergreen

Focus Monthly (Visitint and Softcolors)

- Chord Diameter: 14.0 mm
- Center Thickness: 0.10 mm at all minus powers
  0.15 mm at +3.00D (varies with power)
- Base Curves: 8.6 mm and 8.9 mm
- Powers: -8.00D to +6.00D (0.25D steps: Visitint & Softcolors)
  -8.50D to -15.00D (0.50D steps; Visitint)
- Tints:
  - Visitint: Light blue visibility tint
  - Softcolors: Royal Blue, Aqua and Evergreen

Focus Monthly Toric (clear[1] and Visitint)

- Chord Diameter: 14.5 mm
- Center Thickness: 0.14 mm at-3.00D (varies with power)
  0.26 mm at +3.00D (varies with power)
- Base Curves: 8.9 mm and 9.2 mm
- Powers: -6.00D to +4.00D sphere (0.25D steps)
  -1.00D, -1.75D, -2.50D cylinder
  Full circle (10° steps)
- Tints:
  - Visitint: Light blue visibility tint

Focus Progressives (Visitint)

- Chord Diameter: 14.0 mm
- Center Thickness: 0.10 mm at all minus powers
  0.16 mm at +3.00D (varies with power)
- Base Curves: 8.6 mm and 8.9 mm
- Powers: -9.00D to +8.00D sphere (0.25D steps)
  Single Progressive Add
  Effective range up to 3.00D
- Tints:
  - Visitint: Light blue visibility tint

Hereafter, NewVues, NewVues Visitint, and NewVues Softcolors will be referred to as Focus 1-2 Week; Focus Visitint, Focus Softcolors, and Focus Toric will be referred to as Focus Monthly unless product distinction is necessary; and information that applies to these and the Focus Progressives (vifilcon A) products will simply reference the Focus name.

ACTIONS

- When hydrated and placed on the cornea, Focus (vifilcon A) contact lenses act as a refracting medium to focus light rays on the retina.
- Visitint lenses are tinted for visibility purposes to make them easier to see when handling.
- Softcolors lenses are tinted for cosmetic purposes for eye color enhancement.

INDICATIONS (Uses)

Vision Correction:

- Focus (vifilcon A) spherical soft contact lenses are indicated for the optical correction of refractive ametropia in aphakic or not-aphakic persons with non-diseased eyes that are myopic or hyperopic and may have 2.00 diopters (D) or less of astigmatism that does not interfere with visual acuity (**see Description** for currently available power range).
- Focus Toric (vifilcon A) soft contact lenses are indicated for the optical correction of refractive ametropia in aphakic or not-aphakic persons with non-diseased eyes that are myopic or hyperopic and may have 6.00 diopters (D) or less of astigmatism that does not interfere with visual acuity (**see Description** for currently available power range).
- Focus Progressives (vifilcon A) aspheric soft contact lenses are indicated for the optical correction of presbyopia in non-aphakic persons with non-diseased eyes who require a reading addition of +3.00 diopters (D) or less and who may have 2.00 diopters (D) or less of astigmatism that does not interfere with visual acuity (**see Description** for currently available power range).

Wearing Schedules:

- Focus (vifilcon A) contact lenses may be prescribed for either daily wear or extended wear for 1 to 7 days between removal for cleaning, rinsing, and disinfection (or disposal if Focus 1-2 Week or Focus Progressives lenses are prescribed as disposable wear) as recommended by the eye care professional.

See **WARNINGS** for information about the relationship between wearing schedule and corneal complications.

CONTRAINDICATIONS (Reasons not to use):

DO NOT use Focus (vifilcon A) contact lenses when any of the following exists:

- Inflammation of the anterior chamber of the eye.
- Active disease, injury or abnormality affecting the cornea, conjunctiva, or eyelids.
- Microbial infection of the eye.
- Insufficiency of lacrimal secretion (dry eye) that interferes with contact lens wear.
- Corneal hypoesthesia (reduced corneal sensitivity).
- Use of any medication that is contraindicated or interferes with contact lens wear, including eye medications.
- Any systemic disease which may be exacerbated by or interferes with contact lens wear.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses.
- Allergy to any ingredient in a solution which must be used to care for the contact lenses.
- Patient history of recurring eye or eyelid infections, adverse effects associated with contact lens wear, intolerance or abnormal ocular response to contact lens wear.
- If eyes become red or irritated.

WARNINGS

Advise patients of the following warnings pertaining to contact lens wear:

Serious eye injury, scarring of the cornea, and loss of vision may result from problems associated with wearing contact lenses and using contact lens care products. To reduce these risks, emphasize to the patient the need for strict compliance with the lens care regimen including handwashing, proper lens disinfection, cleaning of the lens case, wearing restrictions, wearing schedules, and follow-up visit schedules.

Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. Instruct patients at the dispensing visit and subsequent visits to **immediately** remove their lenses and **promptly** contact their eye care professional if they should experience eye discomfort, foreign body sensation, excessive tearing, vision changes, redness of the eye or other problems with their eyes.

Non-compliance with the manufacturer's labeled lens care instructions may put the patient at significant risk of developing a serious eye infection.

Tap water, distilled water, or homemade saline solution should NOT be used as a substitute for any component in the lens care process. The use of tap and distilled water has been associated with Acanthamoeba keratitis, a corneal infection which is resistant to treatment and cure.

Smoking increases the risk of corneal ulcers for contact lens users,[2,3] especially when lenses are worn overnight or while sleeping.

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[2]. The risk increases with the number of consecutive days that the lenses are worn between removals, even with the first overnight use.

PRECAUTIONS

To prevent damage to the eyes or to the contact lenses, the following precautions should be taken:

Special Precautions to the Eye Care Professional:

- **Eye injury due to irritation or infection may result from lens contamination. To reduce the risk of contamination, review the appropriate manufacturer's labeled lens care instructions with the patient (see Lens Care Directions).**
- The following patients may not be suitable contact lens candidates and/or may experience a higher rate of adverse effects associated with contact lens wear:
  - Patients with a history of non-compliance with contact lens care and disinfection regimen, wearing restrictions, wearing schedule, or follow-up visit schedule.
  - Patients who are unable or unwilling to understand or comply with any directions, warnings, precautions, or restrictions. Contributing factors may include but are not limited to age, infirmity, other mental or physical conditions, and adverse working or living conditions.
  - Patients who would not, or could not, adhere to a recommended care regimen, or who are unable to place and remove lenses, should not be provided with them.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.
- Diabetics may have reduced corneal sensitivity and thus are more prone to corneal injury and do not heal as quickly or completely as non-diabetics.
- Periodic eye examinations are extremely important for contact lens wearers. Conduct appropriate follow-up examinations to determine ocular response, especially for extended wear patients.
- Clinical studies have shown that contact lenses made from the vifilcon A 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 professional should consider all factors that affect lens performance and ocular health. The continuing ocular health of the patient and lens performance on eye should be carefully monitored.
- 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.
- Fluorescein should not be used while the lenses are on the patient's eyes. The lenses absorb this dye and become discolored. Fluorescein in the eye should be thoroughly flushed with a sterile saline solution before the lens is reinserted.

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Eye Care Professionals should carefully instruct patients about the following care regimen and safety precautions:

- Exposure to water while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection, including but not limited to Acanthamoeba keratitis.
- Environmental fumes, smoke, and vapors should be avoided in order to reduce the chance of lens contamination or physical trauma to the cornea.
- Instruct patients to promptly remove a lens to avoid serious injury in the event that a foreign body or other contaminant gets onto the lens or the eye.
- Instruct patients to discard any lens which becomes dehydrated or damaged. Such lenses should not be reinserted due to the risk of corneal irritation or injury.
- Inform patients that eye irritation or infection and damage to lenses may result if cosmetics, lotion, soap, cream, hair spray, deodorant, or aerosol products come in contact with lenses. If sprays are used, eyes should be kept closed until the spray has settled.
- Patients should inform their eye care professionals and employers that contact lenses are worn. Contact lens wear may not be suitable for certain occupations, or, in other instances, may require eye protection equipment.
- Patients should inform their eye care professionals and physicians that contact lenses are worn and should consult the eye care professional before using any medication in the eye.
- Certain medications may cause dryness of the eye, increased lens awareness, lens intolerance, blurred vision or visual changes. These include, but are not limited to, antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness. Caution patients using such medications accordingly and prescribe proper remedial measures.
- Patients should never exceed the prescribed wearing schedule regardless of how comfortable the lenses feel. Doing so increases the risk of adverse effects.
- Do not use lenses past the expiration date.

ADVERSE EFFECTS

Potentially serious complications are usually accompanied by one or more of the following signs and symptoms:

- Foreign body sensation
- Excessive watering or other eye secretions including mucopurulent discharge
- Redness of the eyes
- Photophobia (light sensitivity)
- Burning, stinging, itching or other pain associated with the eyes
- Comfort is less compared to when the lens was first placed on the eye
- Poor visual acuity (reduced sharpness of vision)
- Blurred vision, rainbows or halos around objects
- Feeling of dryness

If the patient notices any of the above signs or symptoms, he or she should be instructed to IMMEDIATELY REMOVE THE LENSES:

- **If the discomfort or problem stops, then look closely at the lens(es):**
  - If the lenses are in any way damaged, DO NOT put the lens(es) back on the eye. Return lenses worn for planned replacement to the storage case, discard damaged disposable lens(es), and contact the eye care practitioner.
  - If the lens has dirt, an eyelash, or other foreign body on it, lenses worn for planned replacement should be thoroughly cleaned, rinsed, and disinfected prior to reinsertion. Disposable lenses should be discarded and replaced with a new lens.
- **If the discomfort or problem continues after removing lens(es), or upon reinsertion, IMMEDIATELY remove lenses and promptly contact the eye care professional for identification of the problem and prompt treatment to avoid serious eye damage.**
- The patient should be instructed **NOT** to use a new lens as self-treatment for the problem.
- Patients should be informed that a serious condition such as corneal ulcer, infection, corneal vascularization, or iritis may be present and may progress rapidly. Less serious reactions such as abrasions, infiltrates and bacterial conjunctivitis must be managed and treated early to avoid more serious complications. Additionally, contact lens wear may be associated with ocular changes which require consideration of discontinuation or restriction of wear. These include but are not limited to local or generalized corneal edema, epithelial microcysts, epithelial staining, infiltrates, neovascularization, endothelial polymegathism, tarsal papillary changes, conjunctival injection or iritis.

ADVERSE EFFECT REPORTING

If a patient experiences any serious adverse effects associated with the use of Focus (vifilcon A) contact lenses, eye care professionals please notify CIBA Vision Corporation at **1-800-241-7468**.

Fitting guides and patient information booklets

- The lens must move adequately on the eye for a proper fit and continued health of the eye. When prescribing Focus lenses for extended wear, it is important to reevaluate the lens fit for adequate movement at various times after the patient sleeps while wearing lenses. This reevaluation should include a follow-up visit as soon as possible after the patient awakens, as well as at other times of the day. If the fit is judged to be too tight or steep, the patient must be refit into a lens which provides the criteria of a well-fitted lens.
- Refer to the appropriate CIBA Vision Professional *Fitting Guide*, which provides detailed fitting information for the lenses described in this package insert. Fitting techniques for other contact lenses may not be applicable to the fitting of these lenses.
- It is strongly recommended that the patient be provided the appropriate *Patient Information Booklet* available from CIBA Vision and understands its contents prior to dispensing the lenses.
- Copies of **Fitting Guides** and **Patient Information Booklets** for Focus lenses are available without charge from: CIBA Vision Corporation, Duluth, Georgia 30097 or by calling a CIBA Vision customer service representative.

LENS REPLACEMENT SCHEDULES

In a **planned replacement program,** the replacement schedule is determined by the eye care professional based upon the patient's physiological condition. CIBA Vision® recommends the following replacement schedule for these lenses when prescribed in a Planned Replacement Program: (The eye care professional may determine a replacement schedule greater or less than these suggested intervals based upon clinical examination of the patient, professional judgment, and clinical experience with the lenses because individual responses to contact lenses vary)

- Focus Monthly:
  - spherical (Visitint and Softcolors): Replace every 1 month
  - Toric (clear and Visitint): Replace every 1 month
- Focus 1-2 Week (NewVues):
  - (clear,Visitint and Softcolors): Replace every 1-2 weeks
- Focus Progressives (Visitint): Replace every 1-2 weeks to 1 month

When Focus 1-2 Week (NewVues) or Focus Progressives lenses are prescribed for **disposable wear** the contact lens is considered a single use medical device in which the lenses are worn from 1 to 7 days and **discarded upon removal** from the eye.

- Focus 1-2 Week (NewVues) for disposable wear: Replace at least every 1 to 7 days
- Focus Progressives for disposable wear: Replace at least every 1 to 7 days

WEARING SCHEDULES

The wearing schedule should be determined by the eye care professional. The maximum suggested wearing time each day should be determined by the eye care professional based upon the patient's physiological eye condition because individual responses to contact lenses vary.

- **DAILY WEAR** (less than one day, while awake):
  - There may be a tendency for the daily wear patient to overwear the lenses initially. Therefore, the importance of adhering to a proper, initial daily wearing schedule should be stressed to these patients. Normal daily wear of lenses assumes a minimum of 6 hours of non-lens wear per 24 hour period.
  - It may be advisable for patients who have never worn contact lenses previously to be given a wearing schedule that gradually increases wearing time over a period of days or weeks. This allows more gradual adaptation of the ocular tissues to contact lens wear.
- **EXTENDED WEAR** (greater than one day, including while asleep): Focus soft contact lenses are indicated for 1 to 7 days between removal for cleaning, rinsing, and disinfection (or disposal if Focus 1-2 Week/NewVues or Focus Progressives are prescribed as disposable wear). Once the lens is removed, the patient's eyes should have a rest period with no overnight lens wear or as recommended by the eye care professional.
- It is suggested that the new contact lens wearer first be evaluated on a daily wear schedule. If the patient is judged to be an acceptable extended wear candidate, the eye care professional may determine an extended wear schedule based upon the response of the patient.
- See **Warnings** for information about the relationship between wearing schedule and corneal complications.

LENS CARE DIRECTIONS

Disposable Wear:

- No lens care is indicated, as lenses are discarded upon removal from the eye.
- Lenses should only be cleaned, rinsed and disinfected on an emergency basis when replacement lenses are not available. (See BASIC INSTRUCTIONS FOR LENS CLEANING, RINSING AND DISINFECTION below.)

Planned Replacement:

- Patients must adhere to a recommended care regimen. Lenses must be cleaned, rinsed, and disinfected after removal and prior to reinsertion on the eye according to the package inserts and patient instructions provided with the lens care products recommended by the eye care professional. Failure to follow the complete regimen in accordance with manufacturer's package inserts and patient instructions may contribute to problems (see ADVERSE EFFECTS) and/or result in the development of serious ocular complications as discussed in WARNINGS.

Basic Instructions for Lens Cleaning and Disinfection:

When lenses are dispensed, the eye care professional should recommend an appropriate system of lens care and provide the patient with instructions according to the package labeling.

- The eye care professional should review the following instructions with the patient:
  - **Lenses must be cleaned, rinsed, and disinfected each time they are removed, for any reason.** If removed while the patient is away from the lens care products, the lenses may not be reinserted, but should be stored until they can be cleaned, rinsed, and redisinfected.
  - **Cleaning** is necessary to remove mucus, film, and contamination from the lens surface. **Rinsing** removes all traces of the cleaner and loosened debris. **Disinfecting** is necessary to destroy remaining microorganisms.
  - Lenses must be cleaned, rinsed, disinfected, and stored in accordance with the package labeling of the lens care products recommended by the eye care professional.
  - Use of an enzyme cleaner is optional and may be recommended by the eye care professional if warranted.
  - A chemical method of disinfection, including AOSEPT®, Quick CARE®, PURE EYES® and SOLO-care™ brand is recommended.
  - Focus contact lenses are not recommended for use with heat disinfection.
  - **To help avoid serious eye injury from contamination:**
    - Always wash, rinse and dry hands before handling the lenses.
    - Use only fresh sterile solutions recommended for use with soft (hydrophilic) contact lenses. When opened, sterile non-preserved solutions must be discarded after the time specified in the label directions.
    - Do not use saliva, tap water, homemade saline solution, distilled water, or anything other than a recommended sterile solution indicated for the care of soft lenses.
    - Do not reuse solutions.
    - Use only fresh solutions for each lens care step. Never add fresh solution to old solution in the lens case.
    - Always empty and rinse the lens case with fresh sterile rinsing or disinfecting solution and allow to air dry. At the next use of the lens case, fill with fresh sterile solution.
    - Replace the lens case at regular intervals to help prevent case contamination by microorganisms which can cause eye infection.
- Never use a hard (rigid) lens solution unless it is also indicated for use with soft contact lenses. Corneal injury may result if hard (rigid) lens solutions not indicated for use with soft lenses are used in the soft lens care regimen.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn to avoid lens dehydration.
- Unless specifically indicated in the labeling, do not alternate, change, or mix lens care systems or solutions for any one pair of lenses. If in doubt as to solution suitability, consult the eye care professional.

CARE FOR A STICKING LENS

If the lens sticks (stops moving) or begins to dry on the eye, instruct the patient to apply several drops of a recommended lubricating solution (used in accordance with package labeling). The patient should wait until the lens begins to move freely on the eye before attempting to remove it. If the lens continues to stick, the patient should IMMEDIATELY consult the eye care professional.

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 patient should: **flush eyes immediately with tap water or fresh saline solution, remove the lenses and place them in the recommended storage solution, and call or visit the eye care professional or a hospital emergency room immediately.**

HOW SUPPLIED

Each lens is packaged in a foil-sealed plastic container containing isotonic phosphate buffered saline solution and is steam sterilized. The package is marked with the base curve, diameter, dioptric power, cylinder and axis (if applicable), tint color (if applicable), manufacturing lot number, and expiration date.

US Corporate Offices:
CIBA Vision Corporation
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[1] Production of clear Focus Toric lenses discontinued in 1998

[2] the CLAO Journal, January 1996, Volume 22, Number 1, pp. 30 - 37

[3] New England Journal of Medicine, September 21, 1989; 321 (12), pp 773 - 783