

BAUSCH & LOMB

SILSOFT®

(elastofilcon A)
Contact Lenses For Aphakic Daily
and Extended Wear

IMPORTANT:

This package insert is effective as of February, 1995 and supersedes all prior inserts for the products described below. Please read it carefully and keep this information for future use.

CAUTION:

Federal Law Prohibits Dispensing Without Prescription.

VISION CORRECTION USE

For BAUSCH & LOMB® SILSOFT® (elastofilcon A) Contact Lenses For Aphakic Daily and Extended Wear.

DESCRIPTION:

For BAUSCH & LOMB® SILSOFT® (elastofilcon A) Contact Lenses are available as spherical lenses. These lenses are hemispherical flexible shells of the following dimensions:

- Chord diameter: 11.3mm to 12.5mm
- Center Thickness: Plus lenses vary in center thickness according to power with thickness always kept to a minimum.
- Powers: See "Indications"

The lens material is a dimethyl diphenyl methylvinyl polysiloxane.

The physical properties of the lens are:

Specific Gravity: 1.13 + 0.03
Refractive Index: 1.44 + 0.02
Light Transmission: Measures greater than 85% - dry

Surface Character: Hydrophilic
Water Content: Approximately 0.2%
*Oxygen Permeability: 340×10^{-11} (cm³ -cm/cm² -sec. -mmHg) at 21°C.

*ASTM D143475 Method

INDICATIONS

Daily Wear

For BAUSCH & LOMB® SILSOFT® (elastofilcon A) Contact Lenses are indicated for vision correction use in aphakic patients with nondiseased eyes who exhibit refractive astigmatism of 1.50 diopters or less and corneal astigmatism of 2.00 diopters or less and can obtain satisfactory visual acuity, in a power range of +7.00 to +35.00 diopters.

Extended Wear

For BAUSCH & LOMB® SILSOFT® (elastofilcon A) Contact Lenses are indicated for extended wear as prescribed by the eye care practitioner for continuous use up to a maximum of 30 days between removals for cleaning and disinfecting. (However, see the "WARNINGS" reference to the relationship between the lens wearing schedule and corneal complications.) The lenses are indicated for the correction of visual acuity in aphakic persons with non-diseased eyes who exhibit refractive astigmatism of 1.50 diopters or less and corneal astigmatism of 2.00 diopters or less and can obtain satisfactory visual acuity, in a power range of +7.00 to +35.00 diopters.

Note: Supplemental spectacles may be required for aphakic persons in some conditions to provide near vision or to compensate for uncorrected refractive astigmatism.

CONTRAINDICATIONS

BAUSCH & LOMB® SILSOFT® (elastofilcon A) Contact Lenses are contraindicated when any of the following conditions exist:

- Inflammation in 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
- Corneal hypoesthesia
- Use of a medication that is contraindicated, including eye medications.
- Patient history of reoccurring eye or eyelid infections including sties, or of adverse effects associated with contact lens wear, or of intolerance or abnormal ocular response to contact lens wear.
- History of patient non-compliance with contact lens care and disinfection regimens, wearing restrictions, wearing schedule, or follow-up visit schedule.
- Patient inability or unwillingness, because of age, infirmity, or other mental or physical conditions, or an adverse working or living environment, to understand or comply with any warnings, precautions, restrictions, or directions.

WARNINGS

Serious eye injury and loss of vision may result from problems associated with wearing contact lenses and using contact lens care products. Therefore, after a thorough eye examination, including appropriate medical background, patients must be fully apprised by the prescribing practitioner of all the risks associated with contact lens wear. To minimize these risks, the need for strict compliance with the care and disinfection regimen including cleaning of the lens case, wearing restrictions, wearing schedules, and follow-up visit schedule must be emphasized to the patient. (See the considerations listed under Contraindications and Precautions.)

Since eye injury can develop rapidly, it is most important that patients be instructed in the possible signs or symptoms of problems and need to remove the lenses and be examined by the prescribing eye care practitioner

or a corneal specialist immediately if they experience any symptoms such as those listed below under Adverse Effects. (Practitioners examining patients presenting such symptoms should see below Important Treatment Information for Adverse Effects.)

Extended Wear: 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. The risk among extended wear lens users increases with the number of consecutive days that the lenses are worn between removals, beginning with the first overnight use. Some researchers believe that these complications are caused by one or more of the following: a weakening of the cornea's resistance to infections, particularly during a closed-eye condition, as a result of hypoxia; an eye environment which is somewhat more conducive to the growth of bacteria and other microorganisms, particularly when a regular periodic lens removal and disinfection or disposal schedule has not been adhered to by the patient; improper lens disinfection or cleaning by the patient; contamination of lens care products; poor personal hygiene by the patient; patient unsuitability to the particular lens or wearing schedule; accumulation of lens deposits; damage to the lens; improper fitting; length of wearing time; and the presence of ocular debris or environmental contaminants. Additionally, smoking increases the risk of ulcerative keratitis in contact lens users.

While the great majority of patients successfully wear contact lenses, extended wear of lenses also is reported to be associated with a higher incidence and degree of epithelial microcysts and infiltrates, and endothelial polymegathism, which require consideration of discontinuation or restriction of extended wear.

The epithelial conditions have been seen to be reversible upon discontinuation of lens wear. The reversibility of endothelial effects of contact lens wear has not yet been established. As a result, practitioner's views of extended wearing times vary from not prescribing extended wear at all to prescribing flexible wearing times from occasional overnight wear to prescribing extended wearing periods from 1 to 7 days for cosmetic extended wear and from 1 to 30 days for aphakic extended wear with specified intervals of no lens wear for certain patients, with follow-up visits, and with a proper care regimen.

PRECAUTIONS

In prescribing contact lenses, the Precautions should be carefully observed. It is also strongly recommended that the practitioner review with the patient the Patient Information Booklet available from Bausch & Lomb prior to dispensing the lenses and assure that the patient understands its contents.

- Contact lens wear may not be suitable for certain occupations, or, in other instances, may require eye protection equipment.
- Environmental fumes, smoke, dust, and vapors, and windy conditions, must be avoided, in order to minimize

the chances of lens contamination or physical trauma to the cornea.

- Hard contact lens solutions not indicated for use with SILSOFT Lenses may not be used in the SILSOFT Lens Care System. If a SILSOFT Lens is worn after soaking in a hard contact lens solution, serious corneal injury may result.
- Chemical disinfection solution may not be used with heat unless specifically indicated in the labeling for heat and chemical disinfection.
- Bausch & Lomb recommends that sterile solutions be used in the SILSOFT Lens Care System. Sterile non-preserved solutions should be used if the patient is allergic to preservatives. When used, sterile non-preserved solutions must be discarded after the time specified in their label directions.
- Eye injury from irritation or infection and damage to lenses may result if cosmetics, lotion, soaps, creams, hair sprays or deodorants come in contact with lenses.
- Eye injury from irritation or infection may result from lens contamination.
- Tweezers or other tools should not be used by patients to remove a lens from the lens container. The lens should be poured into the hand.
- Patients must be instructed on and demonstrate the ability of prompt removal of the lenses.
- Aphakic patients should not be fitted with contact lenses during the post operative period until, in the opinion of the surgeon, the eye has healed completely.
- A lens must move freely on the eye for a proper fit. For further information, see the BAUSCH & LOMB® SILSOFT® (elastofilcon A) Fitting Guide.
- Some patients will not be able to tolerate extended wear even if able to tolerate the same or another lens on a daily wear basis. Patients should be carefully evaluated for extended wear prior to prescription and dispensing, and practitioners should conduct early and frequent follow-up examinations to determine ocular response to extended wear.
- When BAUSCH & LOMB SILSOFT (elastofilcon A) Contact Lenses are worn by persons who subsequently require topical medications to be administered to the eye, the lenses should be removed and cleaned and disinfected prior to being inserted after using medication. No medication or solutions except those prescribed by the eye physician should be used.
- After removal of lenses from the lens case, to prevent contamination and to help avoid serious eye injury, always empty and rinse lens case with fresh rinsing solution and allow to air dry between each lens disinfection cycle.

ADVERSE EFFECTS

The following symptoms may occur:

- eye pain
- eyes sting, burn, or itch (irritation)
- comfort is less than when lens was first placed on eye

- 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
- change in sensitivity to light (photophobia)
- feeling of dryness

The patient should be instructed that if any of the above symptoms occur:

- Immediately remove the lenses
- If the discomfort or problems 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 your eye care practitioner.
- If the lens has dirt, an eyelash or other foreign body on it, or the problem stops and lens appears undamaged, thoroughly clean, rinse and disinfect the lenses; then reinsert them.
- If the above symptoms continue after removal of the lens or upon reinsertion of a lens, the lenses should be removed immediately and the patient should immediately contact their eye care practitioner or a physician, who must determine the need for examination, treatment or referral without delay. (See Important Treatment Information for Adverse Effects.) A serious condition such as infection, corneal ulcer, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, epithelial staining and bacterial conjunctivitis must be managed and treated carefully to avoid complications.

IMPORTANT TREATMENT INFORMATION FOR ADVERSE EFFECTS

Sight-threatening ocular complications associated with contact lens wear can develop rapidly, and therefore early recognition and treatment of problems are critical.

Infectious corneal ulceration is one of the most serious potential complications, and may be ambiguous in its early stage. Signs and symptoms of infectious corneal ulceration include discomfort, pain, inflammation, purulent discharge, sensitivity to light, cells and flare, and corneal infiltrates.

Initial symptoms of a minor abrasion and an early infected ulcer are sometimes similar. Accordingly, such epithelial defects, if not treated properly, may develop into an infected ulcer. In order to prevent serious progression of these conditions, a patient presenting symptoms of abrasions or early ulcers should be evaluated as a potential medical emergency, treated accordingly, and be referred to a corneal specialist when appropriate.

Standard therapy for corneal abrasions such as eye patching or the use of steroids or steroid/antibiotic combinations may exacerbate the condition. If the patient is wearing a contact lens on the affected eye when

examined, the lens should be removed immediately and the lens and lens care products retained for analysis and culturing.

FITTING GUIDES AND PATIENT INFORMATION BOOKLETS

A Bausch & Lomb Fitting Guide provides detailed fitting information for BAUSCH & LOMB® SILSOFT® (elastofilcon A) Contact Lenses. When lenses are dispensed for vision correction, the patient must be supplied with an appropriate cleaning and disinfection regimen, with appropriate written instructions for the care products prescribed. The patient must fully understand all lens care and handling instructions. In addition, it is very important for the eye care practitioner to give the patient the appropriate Patient Information Booklet and review it with the patient. Copies of Fitting Guides and Patient Information Booklets for BAUSCH & LOMB, SILSOFT, (elastofilcon A) Contact Lenses are available without charge from: Bausch & Lomb Incorporated, North American Vision Care, PO Box 450, Rochester, New York 14603-0450. Toll free number: In the Continental U.S., Alaska or Hawaii 1-800-828-9030; In New York State 1-800-462-1720.

WEARING SCHEDULES

It is recommended that contact lens wearers see their eye care practitioner twice each year or if directed, more frequently.

A comfort adaptation period is associated with the BAUSCH & LOMB, SILSOFT, (elastofilcon A) Contact Lens. Comfort obtained with this lens is generally superior to that obtained with hard lenses. The initial comfort usually is not as good as with hydrogel lenses due to lens size and movement. The comfort improves substantially during the adaptation period.

Daily Wear:

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. The wearing schedule should be determined by the eye care practitioner. The wearing schedule chosen by the eye care practitioner should be provided to the patient.

Extended Wear (Greater than 24 hours, or while asleep) Wearing schedule should be determined by the prescribing eye care practitioner for each individual patient, based upon a full examination and patient history as well as the practitioner's experience and professional judgement. Bausch & Lomb recommends beginning extended wear patients with the initial daily wear schedule recommended by the eye care practitioner, followed by a period of daily wear, and then the gradual introduction of extended wear one night at a time, unless individual considerations indicate otherwise. The practitioner should examine the patient in the early stages of extended wear in order to determine corneal response.

The lens must be removed for cleaning and disinfecting at least once every 30 days or more frequently such as one to two weeks, as determined by the prescribing eye care practitioner. (See the factors discussed in the WARNINGS section.) Once removed, the lens should remain out of the eye for a period of rest, overnight or longer, as determined by the prescribing eye care practitioner.

LENS CARE DIRECTIONS

The products and procedures in this insert are recommended by Bausch & Lomb for the care of BAUSCH & LOMB® SILSOFT® (elastofilcon A) Contact Lenses. The care products referred to in this insert have individual package inserts or brochures containing instructions and warnings for its use, which must be read and followed. An eye care practitioner may recommend alternative products and procedures for lens care. If other products and procedures are recommended, specific information on those products should be provided to the patient.

Patients must adhere to a recommended care regimen. Failure to follow the regimen may result in development of serious ocular complications as discussed in the WARNINGS.

Patients who require only vision correction and who would not, or could not, adhere to a recommended care regimen for the lenses, or who are unable to place and remove lenses, should not be provided with them.

When lenses are dispensed, the patient must be provided with an appropriate cleaning and disinfection regimen and appropriate and adequate instructions and warnings for lens care, handling, cleaning, and disinfection. The eye care practitioner should recommend appropriate and adequate procedures and products for each individual patient, in accordance with the particular lens, wearing schedule and disinfection system selected by the practitioner, the specific instructions for such products, and the particular characteristics of the patient.

Basic Instructions for Patient Cleaning and Disinfecting

The eye care practitioner's instructions to the patient concerning cleaning and disinfecting contact lenses should include the following:

- Bausch & Lomb recommends that the patient use one system of lens care, either thermal (heat) or chemical. Unless specifically indicated in the labeling, do not alternate, change or mix lens care systems for any one pair of lens.
- Do not reuse solutions. Use fresh solutions for each step.
- Do not use saliva, tap water, distilled water, or anything other than a recommended sterile solution labeled for the care of SILSOFT lenses.
- Carefully read and follow the Patient Information Booklet
- Lenses must be both cleaned 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 and disinfected. Cleaning is necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful micro-organisms.

- Clean one lens first (always the same lens first to avoid mixups), rinse the lens thoroughly with sterile 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.
- Stored lenses must be disinfected and left in the closed case until ready to wear.
- If the lenses have been stored for more than 24 hours, disinfect immediately before wearing and at least once a week. Put fresh solution inside the lens chamber, completely covering the lenses, before each disinfection.
- After removal of lenses from the lens case, the case should be emptied, rinsed with sterile saline or disinfecting solution, and allowed to air dry. At the next use of the case, fill it with fresh solution. (See Precautions for care of lens case)

Lens Deposits and Use of the Enzymatic Cleaning Procedure

Some wearers, who tend to secrete unusually large amounts of mucus in the lacrimal fluid, may experience a buildup of lens deposits within a few weeks, despite adequate cleaning measures. If medium to heavy surface accumulations of non-removable materials are observed, the affected lenses must be replaced to prevent and increased risk of adverse effects. To minimize deposit accumulations, the practitioner may prescribe an enzymatic cleaning regimen in addition to the regular cleaning regimen.

Deposits characterized as medium, or heavy, have been reported to occur on lens worn for approximately one year. The occurrence of these deposits appears to increase with duration of lens use. These medium or heavy deposits, when they do exist, can be detected by means of slit lamp biomicroscope examination. In order to remove deposits which may form on the lenses, wearers should use enzymatic contact lens cleaning tablets according to the directions for use which accompany the tablets. To help remove tear residues, mucus and other deposits that tend to accumulate on the lens surface, patients should use a recommended cleaning solution according to the directions for use which accompany the product. The practitioner's instructions should emphasize that the lenses must be disinfected after completing all cleaning procedures, including enzymatic cleaning.

Thermal (Heat) Lens Disinfection

- Clean the contact lenses with a recommended cleaning solutions and thoroughly rinse the contact lenses with preservative free saline solution.

- Put each lens into its correct chamber.
- Fill the chamber of the case 2/3 full with the preservative free saline solution. Completely cover the lenses.
- Tightly close the top on each chamber of the lens storage case.
- To disinfect, follow the directions accompanying the disinfection unit and the care regimen recommended by the eye care practitioner. (Discoloration and cracking of lens carrying cases have been reported after varying periods of use. If such occurs, replacement is indicated to avoid interference with the disinfection procedure. The patient should also check the unit as directed in the unit instructions to assure that it is operating at each cycle. Malfunctioning units may not be used, and must be replaced.)
- Leave the lenses in the unopened storage case until cool and the patient is ready to place the lenses on the eyes.

Emergency Method for Heat Disinfection

If a heat disinfection unit is not available, tightly close the lens case and place in a pan of already boiling water. Leave the closed lens case in the pan of boiling water for at least 10 minutes. (Above an altitude of 7,000 feet, boil for at least 15 minutes.) Care must be exercised to not allow the water in the pan to boil away. Remove the pan from the heat and allow it to cool for 30 minutes to complete the disinfection of the lenses. **USE OF HEAT DISINFECTION UNIT SHOULD BE RESUMED AS SOON AS POSSIBLE.**

Chemical Lens Disinfection

- Clean the contact lenses with a recommended cleaning solution and thoroughly rinse the contact lenses with a recommended rinsing solution.
- To disinfect, carefully follow the instructions accompanying the disinfection solution in the care regimen recommended by the eye care practitioner.
- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing.
- **Do not** heat the disinfection solution and lenses. Leave the lenses in the unopened storage case until ready to put on eyes.

Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A 20-second rinse in fresh sterile saline solution should reduce the potential for irritation.

CARE FOR A DEHYDRATED LENS

If a SILSOFT® Contact Lens is exposed to air while off the eye, it may become dry and brittle and need to be rewetted. If the lens is adhering to a surface, such as a counter top, apply saline before handling.

To rewet the lens:

- Handle the lens carefully.
- Place the lens in a storage case and soak the lens in a recommended rinsing and storing solution for at least eight hours.

- Clean and disinfect the rehydrated lens using a recommended lens care system.
- If after soaking, the lens surface remains dry and the lens does not become wettable, the lens should not be used until examined by the eye care practitioner.

PRACTITIONER DISINFECTION OF OPEN LENSES

All lenses that have been opened must be disinfected after each fitting and at least once each week. Unopened lenses are sterile and need not be disinfected until the vial seal has been broken.

HOW SUPPLIED

Each SILSOFT lens is supplied in a glass vial containing sterile purified water. The glass vial is marked with the base curve, dioptric power, diameter, expiration date, and the manufacturing lot number of the lens.

Bausch & Lomb
Rochester, NY 14609-0450

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