# PROFESSIONAL FITTING AND INFORMATION GUIDE

## Select 1 Day (somofilcon A)

## Soft (Hydrophilic) Daily Disposable Contact Lenses with UV Blocker

**IMPORTANT**: This Professional Fitting and Information Guide contain important information and instructions. Please read carefully and keep this information for future use.

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a licensed Eye Care Practitioner.

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## INTRODUCTION

Select 1 Day (somofilcon A) Soft (Hydrophilic) Daily Disposable Contact Lenses with UV Blocker are made from somofilcon A with a water content of 56% and are for daily disposable use.

This Fitting Guide has been developed to provide practitioners with information covering characteristics of Select 1 Day (somofilcon A) Soft (Hydrophilic) Daily Disposable Contact Lenses with UV Blocker and to illustrate fitting procedures. Please read carefully and keep this information for future use.

## PRODUCT DESCRIPTION

Select 1 Day (somofilcon A) Soft (Hydrophilic) Contact Lenses for Daily Disposable Contact Lenses with UV Blocker are a hydrophilic co-polymer of silicone containing monomers and hydrophilic monomers which is cross-linked with tetraethyleneglycol dimethacrylate and di-functional methacryloxypropyl-terminated poly(dimethylsiloxane).

When hydrated, the lens consists of 44.0% somofilcon A and 56.0% water by weight. A benzophenone UV absorbing monomer is used to block UV radiation.

The average transmittance characteristics are less than 5% in the UVB range of 280-315nm and less than 50% in the UVA range of 315-380nm.

The lens contains a UV Blocker and has a hemispherical flexible shell, which covers the cornea and a portion of the adjacent sclera, with the following dimensions:

- Chord Diameter: 13.0 mm to 15.5 mm
- Centre Thickness: 0.03 mm to 0.50 mm
- Base Curve: 7.5 mm to 9.30 mm
- Powers: -20.00D to +20.00D

The physical/optical properties of the lenses are:

- Refractive Index: 1.401 ± 0.005
- Visible Light Transmittance (380-780nm): ≥95%
- UVA Light Transmittance (315-380nm): <50.0%
- UVB Light Transmittance (280-315nm): <5.0%
- Surface Character: Hydrophilic
- Water Content: 56% ± 2%
- Oxygen Permeability (Dk): $60 \times 10^{-11}$ ($cm^2$/sec)(ml $O_2$/ml x mmHg) at 35ºC (Fatt Method for determination of oxygen permeability)
- Specific Gravity: 1.04

## LENS PARAMETERS AVAILABLE

**The lenses are available as follows:**

**Select 1 Day (somofilcon A)**

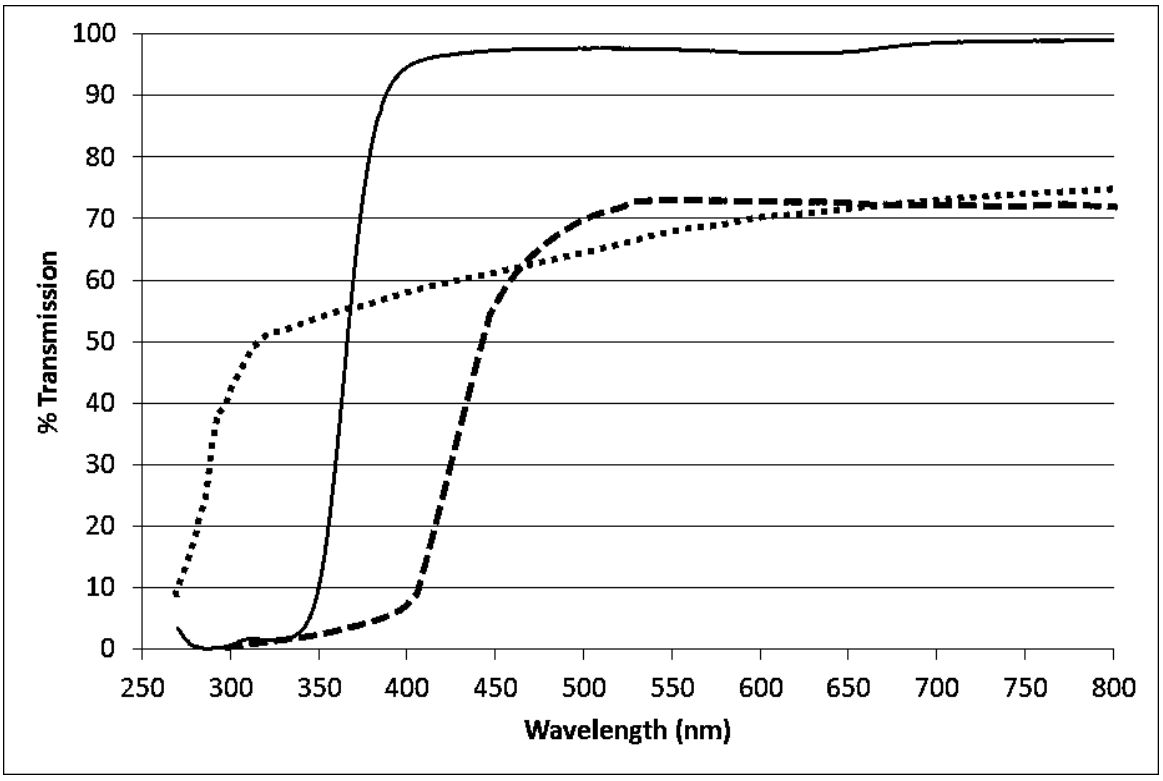
- Sphere Powers: -10.00D to +8.00D
  (-10.00D to -6.50D in 0.50D steps
  -6.00D to -0.25D in 0.25D steps
  +0.25D to +6.00D in 0.25D steps
  +6.50D to +8.00D in 0.50D steps)
- Centre Thickness: varies with power, e.g., 0.07 mm at -3.00D
- Diameter: 14.00 mm
- Base Curve: 8.60 mm

## ACTIONS

In its hydrated state, Select 1 Day (somofilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens with UV Blocker when placed on the cornea acts as a refracting media to focus light rays on the retina.

## TRANSMITTANCE CURVES

The transmittance curve below compares Select 1 Day (somofilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens with UV Blocker, a 24-yr. old human cornea and 25-yr. old human crystalline lens.




**Key:**

Select 1 Day (somofilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens with UV Blocker. The data shown was obtained from measurements taken through the central 3-5 mm portion for the thinnest marketed lens (-6.00DS lens with a centre thickness 0.070mm).

24-year old human cornea[1]

25-year old crystalline lens[2]

1. Lerman, S., *Radiant Energy and the Eye*, MacMillan, New York, 1980, p.58, fig. 2-21
2. Waxler, M., Hitchins, V.M., *Optical Radiation and Visual Health*, CRC Press, Boca Raton, Florida, 1986, p.19, fig. 5

**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 the 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 Practitioner for more information.**

## INDICATIONS (USES)

The **SELECT 1 DAY** (somofilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens with UV Blocker is indicated for daily wear single use only for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

The Eye Care Practitioner should prescribe the lenses for daily wear single use only. The lenses are to be discarded upon removal; therefore, no cleaning or disinfecting is required.

## CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE REACTIONS

**For CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE REACTIONS, see Package Insert PI01002 for Select 1 Day (somofilcon A) Soft (Hydrophilic) Daily Disposable Contact Lenses with UV Blocker.**

## FITTING GUIDELINES

### 1. GENERAL FITTING INSTRUCTIONS

### Patient Selection

- Persons who would not or could not adhere to a recommended care regimen or are unable to place and remove the lenses should not be provided with them. Failure to follow handling and wearing instructions could lead to serious eye infections, which might result in corneal ulcers.

- Patient communication is vital because it relates not only to patient selection, but also to ensuring patient compliance. It is also necessary to discuss the information contained in the Patient Information Booklet with the patient at the time of the initial examination.

- Patients selected to wear the lenses should be chosen for their motivation to wear contact lenses, general health and co-operation. The Eye Care Practitioner must take care in selecting, examining and instructing contact lens patients. Patient hygiene and willingness to follow practitioner instructions are essential to their success.

- Patients who do not meet these criteria should not be provided with contact lenses.

**Pre-fitting Examination**

- A detailed history is crucial to determining patient needs and expectations. Your patient should be questioned regarding vocation, desired lens wearing time (full or part-time), and desired lens usage (reading, recreation or hobbies).

- Initial evaluation of the trial lens should be preceded by a complete eye examination, including visual acuity with and without correction at both distance and near, keratometry and slit lamp examination.

- Perform a preliminary evaluation to determine distance refraction as well as to rule out contraindications to contact lens wear described in the Package Insert.

- Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane.

- Place lens on the eye. Allow the lens to remain on the eye long enough to achieve a state of equilibrium. Small variation in the tonicity, pH or the lens solutions and individual tear composition may cause slight changes in fitting characteristics.

- If the initial lenses selection covers the patient's cornea fully, provides discernible movement (0.10mm to 0.30mm) after blink, is comfortable for the patient and provides satisfactory visual performance, it is a well-fitted lens and can be dispensed (see **Criteria for a Well-Fitted Lens** under **Clinical Assessment** below).

**Clinical Assessment**

1. Criteria for a Well-Fitted Lens:
   - 0.5 to1.0 mm movement in primary gaze
   - 1.0 mm to1.5 mm movement in upgaze
   - centration in primary gaze

2. Characteristics of a Tight Lens
   - <0.5 mm movement in primary or upgaze

3. Characteristics of a Loose Lens
   - >1.0 mm movement in primary gaze
   - >1.5 mm movement in upgaze
   - poor centration in primary and upgaze

- Full coverage of the cornea is defined as the lens edge extending beyond the limbal area in all directions. Initial lens evaluation must be done after at least 10 minutes of lens wear to allow the lens to stabilize and any tearing to subside.

- Following a blink, the lens should move vertically on the patient's eye about 0.1 mm to 0.30 mm. Using a slit lamp this movement can be estimated by comparing it with the 1.0 mm lens peripheral bevel width.

- When lenses are dispensed for vision correction, the wearer must be supplied with an appropriate wearing regimen and must fully understand all lens handling and emergency lens care instructions to prevent lens damage as described in the Package Insert and the Patient Information Booklet.

**Follow-up Care**

a) Follow-up examinations are necessary to ensure continued successful contact lens wear. From the day of dispensing and optimum follow-up schedule for daily wear is recommended.
b) Prior to a follow-up examination, the contact lens should be worn for at least 6 to 8 hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear.
c) With lenses in place on the eyes, evaluate a fitting performance to assure that **Criteria for a Well-Fitted Lens** continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.
d) After lens removal, instill sodium fluorescein (unless contraindicated) into the eyes and conduct a thorough biomicroscopy examination.
    - Presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive cornea edema.
    - Presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, excessive lens wear and/or poorly fitting lens.
    - Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

If any of the above observations are judged abnormal, various professional judgements are necessary to alleviate the problem and restore the eye to optimal conditions. If the **Criteria of a Well-Fitted Lens** is not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

## 2. SPHERICAL LENS FITTING GUIDELINES

A spherical over-refraction should be performed to determine the final lens power after the lens fit is judged acceptable. The spherical over-refraction should be combined with the trial lens power to determine the final lens prescription. The patient should experience good visual acuity with the correct lens power unless there is excessive residual astigmatism.

If vision is acceptable, perform a slit lamp examination to assess adequate fit (centration and movement). If fit is acceptable dispense the lenses instructing the patient to return in one week for assessment.

## 3. MONOVISION (SPHERICAL FITTING GUIDELINES)

### 1. Patient Selection

**A. Monovision Needs Assessment**

For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient with significant astigmatism (greater than one diopter) in one eye may not be a good candidate for monovision.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis), it should be determined by trial whether this patient can function adequately with monovision. Monovision contact lens wear may not be optimal for such activities as:

(1) Visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and

(2) Driving automobiles (e.g., driving at night). Patients who cannot pass their state driver's license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

**B. Patient Education**

Not all patients function equally well with monovision correction. Patients may not perform with this correction as they have with bifocal reading glasses. Each patient should understand that monovision, as well as other presbyopic contact lenses, or other alternative, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process, it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

### 2. Eye Selection

Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used.

A. Ocular Preference Determination Methods

Method 1 – Determine which eye is the "sight eye." Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

Method 2 – Determine which eye will accept the added power with the least reduction in vision. Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.

B. Refractive Error Method

For anisometropic corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

C. Visual Demands Method

Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction correct the eye on that side for near.

Example:

A secretary who places copy to the left side of the desk will usually function best with the near lens on the left eye.

## 3. Special Fitting Considerations

**Unilateral Lens Correction:**
There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may require only a distance lens.

Example:

A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 lens on the near eye and the other left without a lens.

A presbyopic patient requiring a +1.50 diopter add who is –2.50 diopters myopic in the right eye and –1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

## 4. Near Add Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading-distance. However, when more than one power provides optimal reading-performance, prescribe the least plus (most minus) of the powers.

## 5. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines and a base curve selection described in the earlier guide.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near add. With trial lenses of the proper power in place observe the reaction to this mode of correction.

Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have

the patient look at familiar near objects, such as a watch face or fingernails. Again, assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reactions. Only after these vision tasks are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g., typewritten copy) at first and then graduate to news print and finally smaller type sizes.

After the patient's performance under the above conditions is completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

## 6. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process, the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

## 7. Other Suggestions

The success of the monovision technique may be further improved by having your patient follow the suggestions below:

- Having a third contact lens (distance power) to use when critical distance viewing is needed.
- Having a third contact lens (near power) to use when critical near viewing is needed.
- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions:

- Reverse the distance and near eyes if a patient is having trouble adapting.

- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of the clear near vision in straight-ahead and upward gaze with monovision.

Note: The decision to fit a patient with monovision correction is most appropriately left to the Eye Care Practitioner in conjunction with the patient after carefully considering the patient's needs.

## WEARING AND APPOINTMENT SCHEDULE

The 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. Patients should be given a wearing schedule and carefully instructed on the handling and care of their lenses as discussed in the Package Insert. Also, be sure to complete the personal wearing/replacement schedule record in the Patient Information Booklet. The lens must be removed, cleaned, disinfected or disposed of and replaced with a new lens as determined by the prescribing Eye Care Practitioner. (See the factors discussed in the **WARNINGS** section.)

Follow-up examinations are necessary to ensure continued successful contact lens wear and to ascertain the effects of the lenses on the eyes. The following schedule is a suggested guideline for daily wear contact lenses:

- 24 hours post-dispensing
- 7 days
- 1 month
- 3 months
- every 6 months thereafter

## LENS APPLICATION AND REMOVAL

Eye Care Practitioners should carefully instruct patients about the following lens care and safety precautions for application and removal of contact lenses.

Handling Precautions:

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup.
- Advise the patient to always handle the same lens, the right or the left, first in order to avoid mix-ups.

Lens Application:

Eye Care Practitioners should advise patients of the following steps when applying their lenses:

1. Examine the lens to be sure it is moist, clean, clear and free of any nicks or tears.

2. Make sure the lens is not turned inside out. Simply inspect the lens to see if the edges turn out. If they do, the lens is inside out. Should the lens be accidentally placed on the eye inside-out, one of the following signs should signal that the lens is to be removed and replaced correctly:

    - Less than usual comfort
    - The lens folds on the eye
    - Excessive lens movement on blink
    - Blurred vision

Eye Care Practitioners should advise patients of the following technique for applying lenses:

**One Hand Technique:** Place the lens on the index finger. Keeping the head up, look straight ahead, pull down the lower eyelid with the middle finger of the placement hand. Look up steadily at a point above. Then place the lens on the lower white part of the eye. Remove the index finger and slowly release the lower lid. Look down to position the lens properly. Close the eyes for a moment: the lens will center itself on the eye.

**Two Hand Technique:** With the lens on the index finger, use the middle finger of the other hand to pull the upper lid against the brow. Use the middle finger of the placement hand to pull down the lower lid and then place the lens centrally on the eye. While holding this position, look downward to position the lens properly. Slowly release the eyelids.

If the lens feels uncomfortable, look in a mirror and gently place a finger on the edge of the contact lens and slowly slide the lens away from the nose while looking in the opposite direction. Then by blinking, the lens will re-center itself.

If after placement of the lens, the vision is blurred, check the following:

a) Cosmetics or oils on the lens. Clean, rinse, disinfect and place on the eye again.
b) The lens is on the wrong eye.
c) The lens is inside-out (it would also not be as comfortable as normal).

**Lens Removal**

Eye Care Practitioners should advise patients that hands must be washed, rinsed and thoroughly dried with a lint free towel before removing lenses.

**CAUTION:** Always advise patients to be sure that the lens is in the correct position on the eye before trying to remove it (a sample check of the vision, closing one eye at a time, will tell the patient if the lens is in the correct position).

Instruct the patient to look up and slowly pull down the lower lid with the middle finger of the removal hand and place the index finger on the lower edge of the lens. Slide the lens down to the lower white part of the eye. Squeeze the lens lightly between the thumb and the index finger. Avoid sticking the edges of the lens together. Discard the worn lenses.

## LENS CARE DIRECTIONS

**1. Basic Lens Care Instructions**

Eye Care Practitioners should review lens care directions with the patient, including basic lens care information.

It is essential that patients understand and use good hygienic methods in the care and handling of their new lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, hands should be clean and free of any foreign substances when lenses are handled. The procedures are:

- Always, wash, rinse and dry your hands before handling contact lenses.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in your mouth.
- Never rinse your lenses in water from the tap. There are two reasons for this:

    a. Tap water may contain impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
    b. You might lose your lens down the drain.

**For Single Use Daily Wear**

Remember there is no cleaning or disinfection needed with Select 1 Day (somofilcon A) Soft (Hydrophilic) Daily Disposable Contact Lenses with UV Blocker prescribed for daily wear single use wear only. The lenses are to be discarded upon removal and have replacement lenses or spectacles available.

**2. Care for a Sticking (Non-Moving) Lens**

If the lens stops moving or cannot be removed, you should instruct the patient to apply a few drops of the recommended lubricating solution directly to your eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues, the patient is instructed to immediately consult their Eye Care Practitioner.

**3. Care for a Dehydrated Lens**

If a soft, hydrophilic lens is exposed to air while off the eye; it may become dry and brittle. If this happens, dispose of the lens and use a fresh one.

**4. Emergencies**

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes, you should: **FLUSH EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVE LENSES PROMPTLY. CONTACT YOUR EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

## HOW SUPPLIED

Each lens is supplied sterile in a blister pack containing isotonic saline solution with 0.005% or 0.020% w/v poloxamer 407 added. The blister pack is labelled with the base curve, diameter, dioptric power, manufacturing lot number, and expiration date of the lens, and the presence of a UV-blocker is noted.

Do not use if blister pack has been broken or damaged.

## REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients should be reported to:

CooperVision
Attn: Product Services
711 North Road
Scottsville, New York 14546
(800) 341-2020
www.coopervision.com