52 1-Day Trial
(ocufilcon B) Soft (Hydrophilic)
UV Blocking Contact lens
For Daily Wear

IMPORTANT: Please read carefully and keep this information for future use. This package insert is intended for the eye care practitioner, but should be made available to patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

Symbol	Description
Rx ONLY	CAUTION: Federal (U.S.A.) Law restricts this device to sale by, or on the order of a licensed practitioner.
	See Instruction Leaflet
6	Use by date (expiration date)
LOT.	Batch code
STERILE	Sterile using steam heat

DESCRIPTION

The 52 1-Day Trial®52 (ocufilcon B) Soft (Hydrophilic) UV Blocking Contact Lens is available in a Sphere design. The lens material (ocufilcon B) is a random copolymer of 2-hydroxyethylmethacrylate and methacrylic acid. A benzophenone UV absorbing monomer is used to block UV radiation.

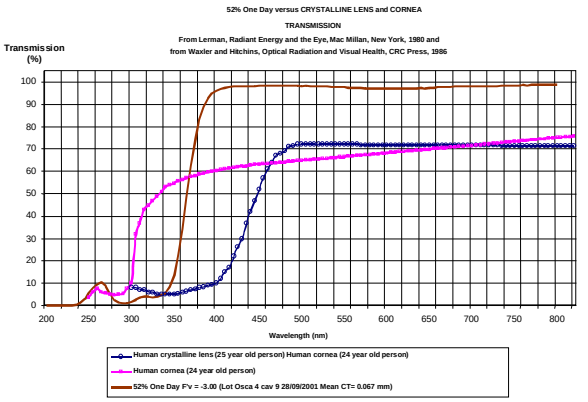
The 52 1-Day Trial®52 (ocufilcon B) Soft (Hydrophilic) UV Blocking Contact Lens is a hemispherical shell of the following dimensions:

- Diameter: 12.0mm to 15.0mm
- Base Curve: 8.00mm to 9.2mm
- Center Thickness: 0.025 mm to 0.27 mm
- Powers: Sphere - 10.00D to +6.00D

The physical/optical properties of the lens are:

- Refractive Indes: 1.41
- Light Transmittance: 97.7% average
- Surface Character: Hydrophilic
- Water Content: 52%
- Oxygen Permeability: $16.8x10^{-11}$ $(cm^2/sec)(mlO_2/ml \times mm\ Hg)$ at 35°C Fatt method (boundary corrected, edge corrected)

UV Absorber



1. Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p. 58, figure 2-21
2. Waxler M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 10, figure 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 absorbing eyewear as directed.

ACTIONS

When placed on the cornea in its hydrated state, the 52 1-Day Trial® 52 contact Lens acts as a refracting medium to focus light rays on the retina.
The thinnest 52 1-Day Trial® 52 contact lenses (-2.25 to -10.00 D) blocks 70% of UVA radiation and 96% UVB radiation average across the spectrum. The radiation blockage of the 52 1-Day Trial® UV lenses will increase for thicker lenses.

Note: Long term exposure to the 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 the outdoor activities). UV- absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye care practitioner for more information.

INDICATIONS (USES)

Spherical:
52 1-DAY TRIAL® 52 (ocufilcon B) Soft (Hydrophilic) UV Blocking Contact lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of 2.00 diopters that does not interfere with visual acuity.

The lens may be prescribed for Daily Wear in not- aphakic persons. The eyecare practitioner may prescribe the contact lens for single use disposable wear (SEE WEARING SCHEDULE).

The 52 1-DAY TRIAL® 52 (ocufilcon B) Soft (Hydrophilic) UV Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the 52 1-Day Trial® UV 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 non-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 thimerosal, mercury or chlohexidine, in a solution which is to be used to care for the 52 1-Day Trial® *UV* Contact Lens
- Any active corneal infection (bacterial, fungal, protozoal or viral)
- If eyes become red or irritated
- The patient is unable to follow lens care regimen or unable to obtain assistance to do so.

WARNINGS

Patients should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that patients follow their eyecare practitioner's directions and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.
- All contact lens wearers must see their eyecare practitioners as directed.
- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that risk of serious adverse reactions is increased when these lenses are worn overnight.
- When daily wear users wear their lenses overnight (outside the approved indication), the risk of ulcerative keratitis is greater than among those who do not wear them overnight.
- **The risk of ulcerative keratitis has been shown to be greater among users for extended wear contact lens users than for daily wear users.**
- Studies have been shown that contact lens users who smoke have a higher incidence of adverse reactions than non-smokers.
- If patients experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, they should be instructed to immediately remove their lenses and promptly contact their eye care practitioner.

PRECAUTIONS

Special Precautions for Eye Care Practitioners:

- Due to their number, all refractive powers, design configurations or lens parameters available in the lens material have not been evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness and optic zone diameter.
  The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.
- Patients who wear 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, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.
- Before leaving the eye care practitioner's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.
- Eye care practitioners should instruct the patient to remove the lenses immediately if the eyes become red or irritated.
- If the lens sticks (stops moving) on the eye, follow the recommended directions in 'Care for a Sticking Lens'. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to **immediately** consult his or her eye care practitioner.
- 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. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch the contact lenses with the fingers or hands if they are not free of foreign materials, as microscopic scratches of the lenses may occur, which causes distorted vision and/or injury to the eye.
- Carefully follow the handling and wearing instructions in the 'Patient Instruction Guide' for the 52 1-Day Trial® *UV* Contact Lens and those prescribed by the eye care practitioner.
- Never wear lenses beyond the period recommended by the eye care practitioner.
- If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses carefully and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.

- Ask the eye care practitioner about wearing lenses during sporting activities.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Always contact the eye care practitioner before using any medicine in the eyes.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- Certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers and those for motion sickness, may cause dryness of the eye, increased lens awareness or blurred vision. Should such conditions exist, proper remedial measures should be prescribed. Depending on the severity, this could include the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medication is being used.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

ADVERSE REACTIONS

The patient should be informed that the following problems may occur when wearing contact lenses:

- The eye may burn, sting and/or itch.
- There may be less comfort than when the lens was first placed on the eye.
- There may be a feeling of something in the eye (foreign body, scratched area).
- There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers and corneal erosion. There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal abnormalities, iritis and conjunctivitis, some of which are clinically acceptable in low amounts.
- There may be excessive watering, unusual eye secretions, or redness of the eye.
- Poor visual acuity, blurred vision, rainbows, or halos around objects, photophobia, or dry eyes may also occur if the lenses are worn for too long a time.

If the patient reports any problems, he or she should be instructed to **IMMEDIATELY REMOVE THE LENS**.
If the discomfort or problem stops, the patient should then look closely at the lens.

- If the lens is in any way damaged, the patient SHOULD NOT put the lens back on the eye. The patient should discard the lens and insert a new fresh lens on the eye.

After reinsertion, if the problem continues, the patient SHOULD NOT put the lens back on the eye but **IMMEDIATELY CONSULT HIS OR HER EYE CARE PRACTITIONER**.
The patient should be advised that when any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. He or she should be instructed **to keep the lens off the eye and to seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

FITTING

Conventional methods of fitting contact lenses apply to the 52 1-Day Trial®52 (ocufilcon B) Soft (Hydrophilic) UV Blocking Contact Lens. For a detailed description of the fitting techniques, refer to the The 52 1-Day Trial®52 (ocufilcon B) Soft (Hydrophilic) UV Blocking Contact Lens Contact Lens **Professional Fitting Guide and the Patient Information Booklet: Single Use Daily Disposable Program**", copies of which are available from:

CooperVision
711 North Road
Scottsville, NY 14546
1-800-341-2020
www.coopervision.com

WEARING SCHEDULE

The eye care practitioner should determine the wearing and replacement schedules.
Patients tend to over wear the lenses initially. The eye care practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner, are also extremely important.
The 52 1-Day Trial®52 (ocufilcon B) Soft (Hydrophilic) UV Blocking Contact Lens Contact Lenses are indicated for daily wear (less than 24 hours while awake).

LENS CARE DIRECTIONS

Eye care practitioners should review with the patient that no cleaning or disinfection is needed with disposable lenses. Patients should always dispose of the lenses when they are removed and have replacement lenses or spectacles available.

CARE FOR A DRIED OUT (DEHYDRATED) LENS

If a 52 1-Day Trial®52 Contact Lens is off the eye and exposed to air from 30 minutes to 1 hour or more, its surface will become dry and gradually become non-wetting. If this should occur, discard the lens and use a new one.

CARE FOR A STICKING (NON-MOVING) LENS

If the lens sticks (stops moving or cannot be removed), the patient should be instructed to apply a few drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after a few minutes, the patient should **immediately** consult the eye care practitioner.

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 AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

Each sterile lens is supplied in a foil-sealed blister package containing normal buffered saline solution. The blister package is labeled with the base curve, diameter, dioptric power, lot number and expiration date of the lens.

Do not use if the package has been broken or damaged.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in-patients wearing the 52 1-Day Trial®52 (ocufilcon B) Soft (Hydrophilic) UV Blocking Contact Lens or experienced with the lenses should be reported to:

CooperVision | SEE BEYOND THE ORDINARY™

711 North Road
Scottsville, NY 14546
1-800-341-2020

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