

medivue clear 1 day (somofilcon A) Soft Contact Lens

Package Inserts

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.

SYMBOLS KEY:

The following symbols may appear on the label or carton.

SYMBOL	DEFINITION
	Caution: this device to sale by or on the order of a licensed practitioner
	See Instructions for Wearers
	Use by Date (expiration date)
	Batch Code
	Sterile using Steam Heat
	UV Blocking

DESCRIPTION

medivue clear 1 day (somofilcon A) Soft Contact Lenses for Daily Wear Single Use is a hydrophilic co-polymer of silicone containing monomers and hydrophilic monomers which is cross-linked with tetraethyleneglycol dimethacrylate.

When hydrated the lens consists of 44.0% somofilcon A and 56.0% water by weight of saline immersed in normal saline. A benzophenone UV absorbing monomer is used in the contact lens to help protect against transmission of harmful UV radiation and medivue clear **1 day** (somofilcon A) Soft Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

The average transmittance characteristics are less than 5% in the UVB range of 280 to 315nm and less than 50% in the UVA range of 316-380nm.

Lenses parameters for **Myopia/Hyperopia:**

- o Diameter: 13.0mm to 15.5mm
- o Basic Curve: 7.50mm to 9.30mm
- o Center Thickness: varies with power e.g. 0.07mm (at -3.00 DS)
- o Powers: -20.00D to +20.00D

Lenses parameters for **Astigmatism:**

- o Diameter: 13.0mm to 15.5mm
- o Basic Curve: 7.50mm to 9.30mm
- o Center Thickness: varies with power e.g. 0.105mm (at -3.00 DS)
- o Powers: -20.00D to +20.00D
- o Cylinder Options -0.75, -1.25, -1.75, -2.25
- o Axis 10° to 180° (10° steps)

Lenses parameters for **Presbyopia:**

- o Diameter: 13.0mm to 15.5mm
- o Basic Curve: 7.50mm to 9.30mm
- o Center Thickness: varies with power e.g. 0.07mm (at -3.00 DS)
- o Powers: -20.00D to +20.00D

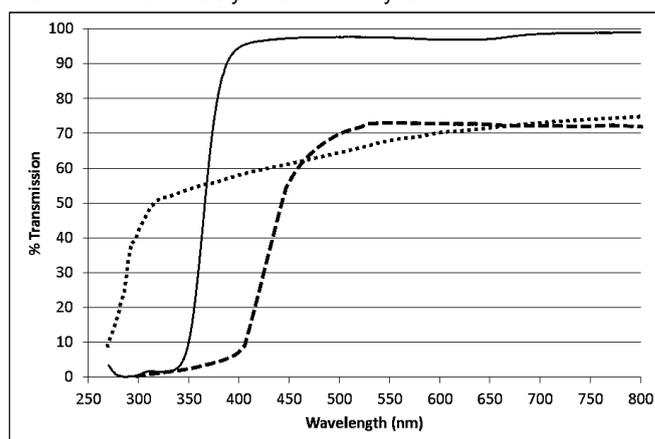
- o Addition Powers: "low" for spectacle near ADD lens (Max +2.25 ADD)
"high" for spectacle near ADD lens (+2.50 ADD or greater)

The physical/optical properties of the lens are:

- o Refractive Index: 1.4003
- o %Transmittance @ 590nm: 98.13
- o %Transmittance @ 280-315nm: 0.71
- o %Transmittance @ 316-380nm: 20.62
- o Surface Character: Hydrophilic
- o Water Content: 56%
- o Oxygen Permeability (Dk): 60×10^{-11} (cm²/sec) (ml O₂/ml mmHg) at 35°C (Fatt method for determination of oxygen permeability)

TRANSMITTANCE CURVES

The transmittance curve below compares **medivue clear 1 day** (somofilcon A) Soft Contact Lenses with UV Blocker, a 24 yr. old human cornea and 25 yr. old human crystalline lens.



Key

- **medivue clear 1 day** (somofilcon A) Soft Contact Lenses 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 0.070 mm)
- 24 years old human cornea¹
- 25 years old crystalline lens²

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.10, 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 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 eyecare practitioner for more information.

INDICATIONS (USES)

The **medivue clear 1 day for Myopia/Hyperopia** (somofilcon A) Soft Contact Lens 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 **medivue clear 1 day for Astigmatism** (somofilcon A) Soft Contact Lens is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 10.00 Diopters.

The **medivue clear 1 day for Presbyopia** (somofilcon A) Soft Contact Lens is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes that may require a reading addition of +3.00 Diopters or less and may exhibit astigmatism up to 1.50 Diopters or less.

medivue clear 1 day (somofilcon A) Soft Contact Lenses with UV blocker help protect against transmission of harmful UV radiation to the cornea and into the eye.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE your contact lenses 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
- Insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity)
- 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
- Any active corneal infection (bacterial, fungal, protozoal, or viral)
- If the eyes become red or irritated

WARNINGS

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

- Problems with contact lenses or lens care products could result in serious injury to the eye. Proper use and care of your contact lenses and lens care products, including lens cases are essential for the safe use of these products.
- Eye problems, including a sore or lesion on the cornea (corneal ulcers) can develop rapidly and lead to loss of vision.
- The risk of an infected sore or lesion on the cornea (ulcerative keratitis) is greater for people who wear extended wear contact

lenses than for those who wear daily wear lenses. Do not wear your lenses while sleeping as the risk of sore or lesion on the cornea (ulcerative keratitis) is greater than among those who do not wear them while sleeping.

- The risk of ulcerative keratitis among contact lens users who smoke is greater than among non-smokers.
- If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, you should immediately remove the lenses and promptly contact your eyecare practitioner. It is recommended that you see your eyecare practitioner routinely as directed.
- **Water Activity** – Do not expose your contact lenses to water while you are wearing them.

Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If your lenses have been submersed in water when swimming in pools, lakes or oceans, you should discard them and replace them with a new pair. Ask your eye care practitioner (professional) for recommendations about wearing your lenses during any activity involving water.

PRECAUTIONS

At your initial visit to your eyecare practitioner:

- Be sure you read and understand the full contents of this booklet and discuss it with your eyecare practitioner.
- Give your eyecare practitioner a complete history of your eye health, including any eye injuries, diseases, conditions or other problems you have had with your eyes, even if they seem unimportant to you.
- Tell your eyecare practitioner about your general health, any medicines you are taking, current treatment by a physician, any disease you had or now have and any prior surgery.
- Before leaving the eyecare practitioner's office, you should be able to promptly remove lenses or should have someone else available who can remove the lenses.

Lens Handling Precautions:

- **Always wash and rinse your hands before handling lenses.** Do not get cosmetics, lotions, soaps, creams, deodorants or sprays in your eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to cause damage lenses than oil base products.
- **Do not** touch contact lenses with your fingers or hands if your hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- **Do not** touch the lens with your fingernails.
- **Carefully** follow the handling, insertion, removal and wearing instructions in this booklet and those prescribed by your eyecare practitioner.
- **Always** handle lenses gently and avoid dropping them.
- **Never** use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into your hand when removing from lens blister

Lens Wearing Precautions:

- You should remove your lenses immediately if your eyes become red or irritated.
- **Never** wear lenses beyond the period recommended by your eyecare practitioner.
- **Always** discard lenses worn as prescribed by your eyecare practitioner.
- If aerosol products such as hair spray are used while wearing

lenses, exercise caution and keep **your eyes closed** until the spray has settled.

- **Avoid** all harmful or irritating vapours and fumes while wearing lenses.
- **Avoid** rubbing your eyes with the lenses on, this can irritate your eye or dislodge the lens.
- **Keep** your eyes closed tightly when washing or showering to keep water and soaps out of your eyes, these may cause loss of the senses, contamination or injury to your eyes.
- **Always** contact your eyecare practitioner before using any medicine in the eyes.
- **Ask** your eyecare practitioner whether there are any other wearing restrictions that apply to you.

Follow-up visits to your eyecare practitioner:

- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. Be sure to keep your follow-up appointments.
- When you return for follow-up visits, be sure to tell your eye care practitioner if your eyes have felt dry, irritated or anything other than completely comfortable while wearing your contact lenses.
- If there is any question in your mind about your wearing schedule and restrictions, cleaning lens handling procedures, lens replacement programme, the condition of your lenses, your follow-up visit schedule, or anything else about contact lens wear, be sure to discuss the subject with your eyecare practitioner, who is there to help you and see you use your contact lenses safely and properly.
- If your eye care practitioner puts a dye or drops in your eyes during the examination, ask when you may be reinsert the lenses. The use of most dyes or drops will require a waiting period before the lenses may be reinserted.

Who should know that you are wearing Contact Lenses?

- Inform your doctor (health care professional) about being a contact lens wearer.
- Always inform your 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.

ADVERSE EFFECTS

Be aware that the following problems may occur when wearing contact lenses:

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

If you notice any of the above symptoms:

- **Immediately remove the lenses.**

- If the discomfort or problem stops, look closely at the lens.
- If the lens is in any way damaged, do not put the lens back on your eye. You should discard the lens and insert a new fresh lens on your eye.
- If your lens has dirt, an eyelash, or foreign body on it, or the problem stops and the lens appears undamaged, you should dispose of the lens and insert a new fresh lens.
- If the problem continues, you should not put the lens back on your eye but immediately consult your eye care professional.
- When any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularisation or iritis may be present. **Seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

FITTING

Conventional methods of fitting contact lenses apply. For a detailed description of the fitting techniques, refer to the Patient Instructions Guide, copies of which are available from:

WEARING AND APPOINTMENT SCHEDULE

Your eyecare practitioner should prescribe the lenses for daily wear single use only. Your eyecare practitioner will determine your wearing schedule.

The maximum suggested daily wearing time for the lenses is:

Day	1	2	3	4	5
Hour	4	5	6	7	8
Day	6	7	8	9	10 and after
Hour	9	10	11	12	all waking hours

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 appointment schedule is a suggested guideline:

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

LENS CARE DIRECTIONS

1. Basic Lens Care Instructions

Eyecare practitioners should review lens care directions with you, including basic lens care information.

It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substances when you handle your lenses. 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

medivue clear 1 day (somofilcon A) Soft Contact Lenses prescribed for daily wear single use wear only. The lenses are to be discarded upon removal and have replacement lenses or spectacles available.

Telephone: (852) 37180699

Fax: (852) 24261177

2. Care For a Sticking (Non-Moving) Lens

If the lens stops moving or cannot be removed, you should be instructed to apply a few drops of the recommended lubricating solution directly to your eye and wait until the lens begins to move freely on your eye before removing it. If non-movement of the lens continues, you should immediately consult your eyecare 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 EYECARE 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% w/v poloxamer 407 added. The blister pack is labelled with the base curve, diopter for spherical lenses or toric power, cylinder axis for toric lenses, multifocal add for multifocal lenses, diameter, lot number, UV blocker and expiration date of the product.

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:

[Manufacturer]

Cooperision, Inc.

711 North Road, Scottsville, New York 14546, USA

[Manufacturing Site]

1) CooperVision, Inc.

711 North Road, Scottsville, New York 14546, USA

2) CooperVision Manufacturing Ltd.

South Point, Hamble, Southampton, S031 4RF, United Kingdom

3) CooperVision CL KFT

Gorcsev Iván street 7, Building C, 2360 Gyál, Hungary

4) CooperVision Puerto Rico LLC

500 Road 584, Lot 7, Amuelas Industrial Park, Juana Diaz, 00795 Puerto Rico, USA

5) CooperVision Costa Rica, SRL

Zonal Franca El Coyoil, Building 53, Alajuela 20101, Costa Rica

[Local Responsible Person]

CooperVision (HK) Ltd.

Unit Nos. 1805-1806, Level 18, 909 Cheung Sha Wan Road, Kowloon, Hong Kong