SOFT CONTACT LENSES: INSTRUCTION FOR USE

A Guide to Soft Contact Lens Wear



Fig. 1



Fig. 2





Sponsor:

CooperVision Australia Pty Ltd 115 Hayward Avenue, Torrensville SA 5031, Australia

Legal Manufacturer:

CooperVision Manufacturing Limited, South Point, Hamble, Southampton, SO31 4RF, UK



Australia: www.coopervision.net.au New Zealand: www.coopervision.co.nz

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Soft contact lenses in buffered saline.

Daily Disposal Contact Lenses Material Family Name and Lens Design:

- ocufilcon B: Sphere
- ocufilcon D: Sphere; Toric
- somofilcon A: Sphere; Asphere; Multifocal; Toric
- stenfilcon A: Asphere; Multifocal; Toric
- omafilcon A: Sphere; Multifocal
- riofilcon A: Sphere

Frequent Replacement Contact Lenses Material Family Name and Lens Design:

- comfilcon A: Sphere / XR; Asphere; Multifocal; Toric / XR Toric; Toric Multifocal
- ocufilcon D: Sphere; Asphere; Toric
- methafilcon A: Asphere; Toric
- fanfilcon A: Sphere; Toric
- somofilcon A: Asphere; Multifocal; Multifocal Toric / Multifocal Toric XR; Toric / XR Toric
- omafilcon B: Sphere; Multifocal; Multifocal XR; Multifocal Toric; Toric / Toric XR

Intended Use / Purpose: For the correction of ametropia¹ in healthy eyes in order to improve visual acuity.

Indication for Use: For the correction of ametropia¹ in healthy eyes.

- Daily Disposable Lenses: For single use daily wear (less than 24 hours, while awake). Lenses should be discarded upon removal.
- Frequent Replacement Lenses: For daily wear (less than 24 hours, while awake). Lenses should be cleaned and disinfected after removal. One-month replacement is recommended. **Comfilcon A lenses** may also be used for extended wear for up to 6 nights / 7 days.

There is no specific restriction on age; suitability should be determined by an eye care professional. **Target User Group** / **Intended Users:** For users with ametropia¹ with healthy eyes requiring vision correction. There is no restriction on age; suitability should be determined by an eye care professional.

Clinical Benefit and Performance Characteristic: Improving visual acuity while wearing the contact lenses. Toric lenses correct astigmatism. Multifocal lenses correct presbyopia.

Mode of Action: Contact lenses are designed to fit over the front surface of the eye (cornea). When placed on the cornea, the contact lens focuses light rays on the retina.

- ¹ Ametropia includes myopia, hyperopia, astigmatism, and presbyopia. The type of ametropia correction depends on the lens type:
 - Sphere / Asphere Lenses: myopia and hyperopia
 - Toric Lenses: myopia and hyperopia, with astigmatism
 - Multifocal Lenses: myopia, hyperopia, and emmetropia with presbyopia
 - Toric Multifocal or Multifocal Toric Lenses: myopia and hyperopia, with astigmatism and presbyopia

MYOPIA MANAGEMENT DAILY DISPOSAL CONTACT LENSES \otimes

Material Family Name: omafilcon A

Intended Use / Purpose: For the correction of ametropia (myopia) and slowing the progression of myopia.

Indication for Use: For the correction of ametropia (myopia) and slowing the progression of myopia in children with healthy eyes in the age range of 6-18 years of age; suitability should be determined by an eye care professional. For single use daily wear (less than 24 hours, while awake). Lenses should be discarded upon removal.

Target User Group / Intended Users: For children with healthy eyes within the age range of 6-18 years, who require myopia correction and want to slow the progression of myopia. Suitability should be determined by an eye care professional.

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Clinical Benefit and Performance Characteristic: Improving visual acuity and slowing the progression of myopia while wearing contact lenses.

Mode of Action: Contact lenses are designed to fit over the front surface of the eye (cornea). When placed on the cornea, the contact lens focuses light rays on the retina and simultaneously provides an optical stimulus to slow the progression of myopia.

Notes:

- Myopia means near- or short-sightedness; hyperopia means far- or long-sightedness; astigmatism
 means the front surface of the eye (cornea) and / or the lens inside the eye has irregular curvature,
 presbyopia means the loss of the ability to change the focus of the lens of the eye, emmetropia
 means no distance correction needed.
- "©" Symbol on labelling indicates the contact lens is for daily disposable wear and not to re-use (for single use only). When symbol is not present, the lens is for frequent replacement wear. Frequent replacement lenses are for a single wearer, multiple use.
- Material family name may be found in the contents statement on labelling.

Contraindications (Reasons Not To Use):

Do not use 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.
- Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic (natural lens of the eye is present).
- Severe insufficiency of lacrimal secretion (dry eyes).
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa (eyelids and lashes) 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 eyes become red or irritated.
- Use of a medication that is contraindicated, including medications for the eye.

Always wash and dry your hands before handling your contact lenses.

Lens Application:

- 1. Do not use if the product sterile barrier system or its packaging is compromised. The sterile barrier for contact lenses is the intact blister seal.
- 2. Before application, ensure the lens is not inside out. Place on your index finger to verify the shape (Fig. 1 & 2).
- 3. Using the middle finger, hold your lower lid down. With the index finger of the other hand, raise upper lid. Place the lens onto the eye (Fig. 3). Repeat for the other eye.

Lens Removal:

Separate the lids with the middle finger of each hand. Look up and with the index finger of the lower hand; slide the lens down onto the white of the eye. Pinch the lens and lift out with the thumb and index finger (Fig. 4). Repeat for the other eye.

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Disinfection/Soaking for Frequent Replacement Contact Lenses:

For lenses worn more than once (single wearer, multiple use) clean and disinfect them strictly following the instructions on your lens care solution bottle or as directed by your eye care professional (for example: ophthalmologist, optometrist, or optician). Follow instructions on the lens care products for proper contact lens case care, including rinsing the lens case with fresh solution and wiping it with a clean tissue or air drying after use. Cases should be replaced as advised on the lens care product instructions.

If Contact Lenses Dry Out:

If contact lenses need rewetting during wear, certain lens care products (used with frequent replacement lenses as indicated) can be used to rewet lenses, or lubricating/rewetting/comfort drops used with soft contact lenses, as recommended by your eye care professional. However, if a lens becomes completely dried out, it should be discarded and replaced with a new one.

Daily Disposable / Single Use Contact Lenses:

Daily disposable lenses are intended to be worn only once, for daily wear, and then discarded.

Precautions:

- For all types of contact lenses, your eye care professional will recommend lens selection, wearing, cleaning and replacement regime. It is recommended to follow your eye care professional's instructions for the duration of use of the contact lens on a daily basis, follow-up visits and emergency procedures. Do not vary these. If in doubt seek the advice of your eye care professional.
- 2. Contact lenses are medical devices and should be fitted by your eye care professional.
- 3. If your eyes become red or irritated, or you experience any pain or unexpected change in vision, remove your lenses immediately and consult your eye care professional.
- 4. Avoid lens wear if you are unwell, in particular with any cold or flu-like symptoms.
- 5. Avoid contaminating lenses with make-up, aerosol sprays or wearing them near noxious fumes.
- 6. Contact lenses should be removed immediately after contact with noxious vapour, e.g. chemical or hazardous substances, or hazardous environment with ocular impact.
- 7. Replace damaged, contaminated or scratched lenses immediately.
- 8. Avoid long nails, which harbour microbes and could damage the eye or lens. A scratched eye is more vulnerable to infection.
- 9. Keep lenses out of the reach of children who are not users.
- 10. Exposure with water (e.g., from the tap, bottled, bath, pool, ocean or during water sports) increases the risk of microbial infection, so do not expose your contact lenses to water, including while wearing them. If they are exposed, the lenses should be discarded and replaced with a new pair.
- 11. Do not change from the lens care solutions recommended by your eye care professional.
- 12. Do not change lens type or parameters without consulting your eye care professional.

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13. Always have a pair of glasses with a current prescription available to use if you become unable to wear your contact lenses, or where contact lens wear is not advised.

Additional Precautions for Frequent Replacement Lenses:

- For lenses worn more than once, always clean and disinfect your lenses as instructed, after lens removal.
- If wearing lenses on an extended wear basis, remove and dispose of your lenses the evening before you are due to replace them, inserting new lenses the following day.

Additional Precautions for Daily Disposable Lenses:

- Daily disposable lenses are not designed to be cleaned or disinfected.
- Daily disposable lenses worn more than once may become damaged or contaminated and could put you at risk of eye infections, inflammation, discomfort, or other problems.

Warnings:

- 1. **DO NOT** sleep in your lenses unless your eye care professional has advised it is safe to
- 2. DO NOT wear your lenses beyond the period recommended by your eye care professional.
- 3. **DO NOT** use household products (e.g., disinfectants) on your lenses.
- 4. DO NOT wear your lenses when using eye drops (unless advised to do so by a medical professional).
- 5. **DO NOT** use saliva to wet your lenses.
- 6. **DO NOT** expose your contact lenses to water while you are wearing them.
- 7. DO NOT rinse or handle your lenses or lens case with or expose them to water as it increases the risk of serious microbial infection.
- 8. **DO NOT** use if the expiry date has passed.
- 9. **DO NOT** share your contact lenses. Sharing lenses greatly increases the chance of eye infections.

Adverse Reactions (Undesirable Side Effects):

You may become aware of the following symptoms while wearing contact lenses:

- Reduced lens comfort or feeling of something in the eye
- Burning, grittiness, itchiness, dryness of the eyes
- Watery eyes and/or unusual eye discharge
- Sensitivity to light (photophobia)
- Swelling or inflammation of the eye (swollen eyelid, eye redness)
- Temporary decrease in vision

What to do when symptoms occur: You should immediately remove the lenses. If the symptoms persist, a serious eye condition may be present. Seek prompt care from your eye care professional so that any potential medical condition can be identified and treated, if necessary, in order to avoid serious eye damage.

PI01033 Page 5 of 6 Revision Date: 2023-02 Medical conditions that may be associated with these symptoms include: corneal abrasion, corneal oedema (swelling), infiltrative keratitis (inflammation of the cornea), corneal infection or ulcer, corneal neovascularisation, and papillary conjunctivitis (eyelid inflammation).

Disposal: use standard waste, recycle whenever possible.

Any serious incident that has occurred in relation to the product should be reported to the manufacturer and applicable competent authority.

SYMBOLS KEY:

The following symbols may appear on the label or carton.

SYMBOL	DEFINITION
R ONLY	Caution: By law, this device must be prescribed by a registered practitioner
\triangle	Caution / See Instructions for Wearers
\square	Use by Date (expiration date)
LOT	Batch Code
STERILE	Sterile using Steam Heat
B L O C K I N G	UV Blocking
BLOCKING	
DW DAILY WEAR	- Daily Wear
DW DAILY WEAR	
	Manufacturer
CE	European Conformity Mark
EC REP	Authorized representative in the European Community
MD	Medical device
®	Do not use if package is damaged
Ţ <u>i</u>	Consult instructions for use
②	Do not re-use
	Recyclable

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