



## PATIENT INSTRUCTION BOOKLET

NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses

CAUTION: THIS PRODUCT FOR SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER

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## INTRODUCTION

Congratulations on choosing the NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses with UV Blocker. Your NaturalVue (etafilcon A) Contact Lenses are made from etafilcon A with a water content of 58% by weight.

Please read this Patient Instruction Booklet carefully. It contains the information you need to know to wear, handle, and care for your NaturalVue (etafilcon A) Contact Lenses. It is essential to your safety that you read and understand the information in this booklet and have your Eye Care Professional answer any questions. Please keep this booklet for future reference.

Your NaturalVue (etafilcon A) Contact Lenses are single-use devices and once removed, they are to be discarded and replaced with a new sterile pair. Your lenses are not intended to be cleaned and disinfected. You should always carry a spare pair of lenses. If you have any questions, always ask your Eye Care Professional.

For your eye health, it is important to wear your lenses as prescribed by your Eye Care Professional. Your Eye Care Professional should be kept fully aware of your medical history. Your Eye Care Professional will tailor a total program of care based on your specific needs. He or she will review with you all instructions for lens handling, including how to open the package safely and easily. You will receive instructions on how to properly insert and remove lenses. This booklet will reinforce those instructions. Discard and replace your contact lenses with a new sterile pair, as prescribed by your Eye Care Professional.

## WEARING RESTRICTIONS AND INDICATIONS

NaturalVue (etafilcon A) Enhanced Multifocal Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia), and/or presbyopia, and myopia progression control in aphakic and/or non-aphakic persons with non-diseased eyes in powers from +20.00 to -20.00 diopters and with non-diseased eyes who may require a reading addition of up to +3.00 D. The powers currently available are +4.00 to -12.25 D. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

NaturalVue (etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

The lenses are intended for single-use disposable wear. Lenses should be discarded after removal from the eye. Clinical studies have shown that there is an increased risk of adverse effects for soft contact lenses that are reused versus those that are discarded after each use.

**DO NOT WEAR YOUR CONTACT LENSES WHILE SLEEPING.**

## 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 your eye.
- Any eye disease, injury, or abnormality that affects your cornea, conjunctiva, or eyelids.
- Severe insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease that may affect your eye or be exaggerated by wearing contact lenses.

- Allergic reactions of ocular surfaces or adnexa (surrounding tissue) that may be induced or exaggerated by wearing contact lenses
- Any active corneal infection (bacterial, fungal, or viral).
- If your eyes become red or irritated.
- Use of any medication that is contraindicated or interferes with your contact lens wear, including ocular medications.
- Allergy to any ingredient in your contact lens material.
- History of recurrent eye or eyelid infections, adverse effects associated with your contact lens wear, intolerance, or an unusual response to your contact lens wear.
- You are unable or unwilling to follow your Eye Care Professionals' directions for removal and disposal of your lenses or unable to obtain assistance to do so.

## WARNINGS

The following warnings pertaining to advice given to you regarding contact lens wear:

- Problems with your contact lenses could result in serious injury to your eye. It is essential that you follow your Eye Care Professional's directions and all labeling instructions for proper use.
- Eye problems, including a sore or lesion on the cornea (corneal ulcers), can develop rapidly and lead to loss of your 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.
- When daily wear users wear their lenses overnight (outside the approved use), the risk of an infected 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, redness of the eye or other problems, you should immediately remove your lenses and promptly contact your Eye Care Professional. It is recommended that you see your Eye Care Professional routinely as directed.

### WARNING:

UV absorbing contact lenses aren't substitutes for protective UV absorbing eyewear, for example UV absorbing goggles or sunglasses, because they don't completely cover the eye and surrounding area. You should continue to use UV absorbing eyewear as directed.

**NOTE: Long term exposure to UV radiation is a part of the risk factors associated with cataracts.** Exposure is according to several factors, for instance environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of 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 Professional for more information.

## PRECAUTIONS

Special Precautions for Your Eye Care Professional:

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not

evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, your Eye Care Professional 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 your ocular health should be carefully weighed against your need for refractive correction; therefore, the continuing ocular health of you and lens performance on your eye should be carefully monitored by your Eye Care Professional.

- Before leaving your Eye Care Professional's office, you should be able to promptly remove lenses or you should have somebody else available who can remove the lenses for you.
- Your Eye Care Professional should instruct you to remove your lenses immediately if your eyes become red or irritated.

Your Eye Care Professional should carefully instruct you:

- If the lens sticks (stops moving) on your eye, follow the recommended directions. Your lens should move freely on your eye for the continued health of your eye. If non-movement of your lens continues, you should immediately consult your Eye Care Professional.
- Always wash, rinse and thoroughly dry hands before handling your lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, aerosol products or hair sprays in your eyes or on your lenses. It is best to put on your lenses before putting on make-up. Water-based cosmetics are less likely to damage lenses than oil-based 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 or injury to your eye.
- Exposure to water while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection. Ask your Eye Care Professional about wearing contact lenses during sporting activities.
- Never wear your lenses beyond the period recommended by your Eye Care Professional.
- If aerosol products such as hair spray are used while wearing your lenses, exercise caution and keep your eyes closed until the spray has settled.
- Always handle your lenses gently and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing your lenses.
- Never use tweezers or other tools to remove your lenses from your lens blister pack unless specifically indicated for that use. Pour the lens into your hand.
- Do not touch the lens with your fingernails.
- Always discard your lenses after the recommended wearing schedule prescribed by your Eye Care Professional. Since these lenses are daily disposable (single use), the lenses must be discarded after removal from the eye.
- Always contact your Eye Care Professional before using any medicine in your eyes.
- Always inform your employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to ensure the continuing health of your eyes. You should be instructed as to a recommended follow-up schedule.
- You should never exceed the prescribed wearing schedule regardless of how comfortable your lenses feel. Doing so increases the risk of adverse effects.
- Do not use your lenses past the expiration date.
- Certain medications may cause dryness of your eye, increased lens awareness, lens intolerance, blurred vision or visual changes.
- Oral contraceptive users could develop visual change or change in lens tolerance when using contact lenses.
- Do not use if the sterile blister package is opened or damaged.

- Never allow anyone to wear your lenses. They have been prescribed to fit your eyes and to correct your vision to the degree necessary. Sharing lenses greatly increases the chance of your eye infections.

### **ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO)**

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

- Your eye stinging, burning, itching (irritation), or other eye pain.
- Comfort is less compared to when lens was first placed on your eye.
- There may be feeling of something in your eye (foreign body, scratched area).
- Excessive watering (tearing) of your eyes.
- Unusual eye secretions.
- Redness of your eyes.
- Reduced sharpness of your vision (poor visual acuity).
- Blurred vision, rainbows, or halos around objects.
- Sensitivity to light (photophobia).
- Feeling of dryness.
- Foreign body sensation.

If you notice any of the above, you should be instructed to:

- Immediately remove your lenses.
- Look closely at your lens. If your lens is in any way damaged, do not put your lens back on your eye. If your lens has dirt, an eyelash, or other foreign body on it, you should thoroughly clean, and rinse your lens; then reinsert it.

After reinsertion, if the problem continues, you should immediately remove your lenses and consult your Eye Care Professional.

- If the above symptoms continue after removal of your lens, or upon insertion of a new lens, you should immediately remove your lens and contact your Eye Care Professional.
- Your Eye Care Professional will examine your eyes, to be certain that a serious condition such as infection, corneal ulcer, neovascularization, or iritis is not present.

### **Important Treatment Information for Adverse Reactions**

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. To prevent serious progression of these conditions, your 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 you are wearing a contact lens on your affected eye when examined, your lens should be removed immediately.

### **PERSONAL CLEANLINESS AND LENS HANDLING**

#### **PREPARING THE LENS FOR WEARING**

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. Your hands should be clean and free of any foreign substances when you handle your lenses. The procedures are:

- Always wash your hands thoroughly with a mild soap, rinse completely and dry with a lint-free towel before touching your lenses.
  - Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses, since these substances may encounter your lenses and interfere with successful wearing.
  - Handle your lenses with your fingertips and be careful to avoid contact with your fingernails. It is helpful to keep your fingernails short and smooth.
- Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.

### **HANDLING THE LENSES**

- Develop the habit of always working with the same lens first to avoid mix-ups.
- Remove your lens from its blister pack and examine it to be sure that it is moist, clean, clear, and free of any nicks or tears.
- Verify that your lens is right side out. Place your lens on your right index finger and verify the orientation correct (see Figures 1 and 2). Your lens should assume a natural, curved, bowl-like shape (Figure 1). If your lens edges tend to point outward (Figure 2), your lens is inside out.

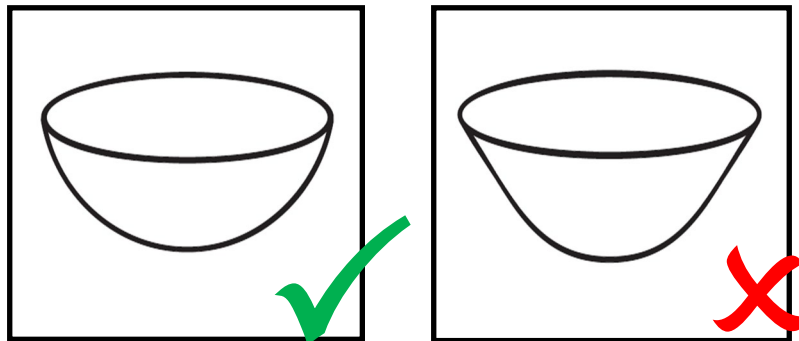


Figure 1

Figure 2

### **PLACING THE LENS ON THE EYE**

To avoid confusion, make it a habit of inserting the same lens first. Check your lens is clean and moist. Check your lens is not inside out. And then follow these steps to apply your lens to your eye:

- Balance your lens on the tip of your forefinger.
- Pull the lower lid down with your middle finger of the same hand.
- Hold the upper lid firmly from above with your middle finger of the other hand. Make sure your finger is placed just where your eyelid meets your eyelashes.
- Your eye is now wide open and the cornea exposed.
- Place your lens directly on your eye. Move your eyes around to help center your lens.
- Release the lower and then the upper lid. Look down and gently close the eyes. Rub the top lid lightly to rub out any trapped air bubbles.
- If your lens is not properly centered on the cornea, gently manipulate by using your fingertips and eyelids.

There are other methods of lens placement. If the above method is difficult for you, your Eye Care Professional will provide you with an alternate method.

**NOTE:** If, after placement of your lens, your vision is blurred, check for the following:



- Your lens is not centered on your eye (see “Centering the Lens”, next in this booklet).
- If your lens is centered, remove your lens (see “Removing the Lens” section) and check for the following:
  - a. Cosmetics or oils on your lens. Dispose of your lens and apply a new fresh lens.
  - b. Your lens is on the wrong eye.
  - c. Your lens is inside-out (it may also not be as comfortable as normal).

If you find that your vision is still blurred after checking the above possibilities, remove your lenses and consult your Eye Care Professional.

### **CENTERING THE LENS**

Very rarely, a lens that is on the cornea will be displaced onto the white part of your eye during lens wear. This can also occur during placement and removal of your lenses if the correct techniques are not performed properly. To center your lens, follow one of the procedures below:

- Close your eyelids and gently massage your lens into place through the closed lids.

**OR**

- Gently manipulate the off-centered lens onto the cornea while your eye is open using your finger pressure on the edge of the upper lid or lower lid.

### **REMOVING THE LENS**

Always remove the same lens first.






- Wash, rinse and dry your hands thoroughly.
- Rewet your contact lens with a few drops of solution to help the lens slide off your eye, especially if it is a little dry.
- Place index finger on your lens.
- Look up.
- Slide lens to white part of your eye using your index finger.
- Gently squeeze your lens between thumb and forefinger to remove your lens.
- Remove the other lens by following the same procedure.
- Daily disposable (single use) lenses are discarded upon removal from your eye each day.

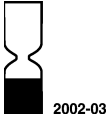






**NOTE:** If this method of removing your lens is difficult for you, your Eye Care Professional will provide you with an alternate method.

### **NON-APPLICABLE MARKETS**

This document is NOT applicable to NaturalVue products sold in Australia, New Zealand, or the United States of America.

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SYMBOL	DESCRIPTION
	Consult instructions for use
	Batch code
	Authorized Representative in the European Community
	CE Mark, indicates product is authorized for sale in the European Community
	Sterilized Using Steam or Dry Heat

SYMBOL	DESCRIPTION
	Use by Date Expressed as: CCYY-MM or CCYY-MM-DD CCYY-MM
	Product to be sold by or on the order of a licensed practitioner.
	UV-Blocking (Indicates the lens is UV blocking)
<b>B.C.</b>	Base Curve (product property)
<b>D</b>	Diopter (Lens Power, product property)
<b>DIA.</b>	Diameter (product property)
	Do not re-use
	Do not re-sterilize
	Manufacturer
	Do not use if package is damaged
<b>ADD</b>	ADD

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