

**BAUSCH + LOMB**

# INFUSE®

## **SPHERICAL**

(kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses

## **MULTIFOCAL**

(kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses

## **ASTIGMATISM**

(kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses

## **PATIENT INFORMATION BOOKLET**

FOR SINGLE USE DISPOSABLE WEAR



**CAUTION:** Federal law restricts this device to sale by or on the order of a licensed practitioner.

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Attention: Read and save the enclosed information.



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# PATIENT INFORMATION BOOKLET

## TABLE OF CONTENTS

|   |    |
|---|----|
| Introduction .....  | 3  |
| Wearing Restrictions and Indications.....                 | 4  |
| Contraindications (Reasons Not to Use).....               | 4  |
| Warnings .....  | 4  |
| Precautions .....   | 5  |
| Adverse Reactions (Problems and What to Do).....          | 6  |
| Personal Cleanliness and Lens Handling.....               | 6  |
| Preparing the Lens for Wearing.....                       | 6  |
| Handling the Lenses.....                                  | 6  |
| Placing the Lens on the Eye.....                          | 7  |
| Centering the Lens.....                                   | 7  |
| Removing the Lens.....                                    | 8  |
| Care for a Sticking (Non-Moving) Lens.....                | 8  |
| Emergencies.....  | 8  |
| Lens Rewetting Products Available From Bausch + Lomb..... | 8  |
| Instructions for the Monovision or Multifocal Wearer..... | 8  |
| Personal Wearing Schedule Record .....                    | 9  |
| Check-Up Visits.....                                      | 10 |
| Eye Care Practitioner Information.....                    | 10 |
| Glossary of Medical Terms.....                            | 11 |
| Symbol Glossary .....                                     | 12 |

# INTRODUCTION

The instructions in this booklet apply to the Bausch + Lomb INFUSE® (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens, the Bausch + Lomb INFUSE® Multifocal (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens, and Bausch + Lomb INFUSE® for Astigmatism (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens. If you have received or are considering another brand of contact lenses, do not use this booklet. Ask your eye care practitioner for the patient booklet or instructions that apply to your brand or type of contact lenses. For the Bausch + Lomb INFUSE® (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses, the Bausch + Lomb INFUSE® Multifocal (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses, and Bausch + Lomb INFUSE® for Astigmatism (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses, it is essential to your safety that you read and understand the information and instructions in this booklet, and have your eye care practitioner answer any questions, both before and after you receive contact lenses.

Wearing contact lenses is different from wearing eyeglasses. Because they are worn directly on your eyes, contact lenses affect the way in which your eyes function. These effects tend to increase with the length of time that the lenses remain on your eyes between removals. Although the great majority of people successfully wear contact lenses without problems, before you decide whether to begin or to continue wearing contact lenses for daily wear, you should discuss with your eye care practitioner the effects of contact lenses on your eyes and the risks associated with wearing contact lenses. You should also read the sections of this booklet entitled "Warnings", "Adverse Reactions (Problems and What to Do)", "Precautions", and "Wearing Restrictions and Indications". Ask your eye care practitioner to explain anything that you do not understand, including any additional restrictions which may be given to you by your eye care practitioner. Your Bausch + Lomb INFUSE® (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses, Bausch + Lomb INFUSE® Multifocal (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses, or Bausch + Lomb INFUSE® for Astigmatism (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lenses have been prescribed for single-use disposable wear, and should be discarded each time lenses are removed from your eyes.

You also need to remember that soft contact lenses, including those covered by this booklet, are made of a type of plastic that absorbs liquids, vapors, and small particles, and, for some people, may collect deposits from your natural eye fluids. Therefore, you should strictly follow the instructions contained in this booklet entitled "Personal Cleanliness and Lens Handling", as well as the written information leaflets accompanying the lens care products that you may buy, and any other instructions given to you by your eye care practitioner. Any failure to follow these instructions and the wearing restrictions will increase the chances of contamination, damage to the lenses, or a build-up of deposits on the lenses, which can lead to serious, sight-threatening eye infections and injuries.

Adherence to your prescribed wearing schedule, and regular check-up visits to your eye care practitioner, are also necessary for the proper and safe use of contact lenses.

It is important to not wear your lenses longer than recommended by your eye care practitioner since doing so increases the risk of adverse effects.

Spaces are provided in the back of this booklet for you to record your personal wearing schedule and schedule of follow-up visits. Soft contact lenses are generally comfortable from the beginning. Therefore, be sure to follow the wearing schedule prescribed for you, and do not over-wear your lenses simply because they remain comfortable and you are not experiencing a problem. Only your eye care practitioner, through a professional examination, can determine how your eyes are reacting to the contact lenses and whether there are any early signs of possible problems.

If problems or symptoms should occur, immediately remove your lenses and follow the steps described in the section of this booklet entitled "Warnings" and "Adverse Reactions (Problems and What to Do)". (Refer to "Glossary of Medical Terms" for description of medical terms used in this booklet.) Prompt attention to problems is essential and may require immediate professional care.

Remember, when wearing soft contact lenses your eyes should look and feel good, and your vision should be clear.

## WEARING RESTRICTIONS AND INDICATIONS

The Bausch + Lomb INFUSE® (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens is indicated for the daily wear correction of refractive ametropia (myopia and hyperopia) in aphakic and/or non-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D.

The Bausch + Lomb INFUSE® Multifocal (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic and/or non-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in powers ranging from +20.00D to -20.00D with add power ranging from +0.75D to +5.00D.

The Bausch + Lomb INFUSE® for Astigmatism (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens is indicated for the daily wear correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes, exhibiting astigmatism of 5.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D.

The lens has been prescribed for single-use disposable wear and is to be discarded after each removal.

## CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the Bausch + Lomb INFUSE® (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens, Bausch + Lomb INFUSE® Multifocal (kalifilcon A) One-Day Soft (Hydrophilic) Contact Lens, or Bausch + Lomb INFUSE® for Astigmatism (kalifilcon A) One-Day Soft (Hydrophilic) 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)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reaction of ocular surfaces or adnexa (surrounding tissue) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated

## WARNINGS

**You should be aware of and fully discuss with your eye care practitioner the following warnings pertaining to contact lens wear:**

- **Problems with contact lenses and lens care products could result in serious injury to your eye.** It is essential that you follow your eye care practitioner's direction 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**.
- Daily wear lenses are not indicated for overnight wear, and **you should not wear lenses while sleeping**. Clinical studies have shown that the risk of serious adverse reactions is increased when daily wear lenses are worn overnight.
- Strict compliance with your wearing restrictions, wearing schedule, and follow-up visit schedule should be followed.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, you should **immediately remove the lenses** and promptly contact your eye care practitioner.
- Do not use if the package is damaged.
- Do not expose your contact lenses to water while wearing them.

**WARNING:** 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 for recommendations about wearing your lenses during any activity involving water.

These lenses contain a Ultraviolet (UV) Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

**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 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.

**NOTE:** The effectiveness of wearing UV-absorbing contact lenses in preventing or reducing the incidence of ocular disorders associated with exposure to UV light has not been established at this time. However, clinical studies have not been done to demonstrate that wearing UV-blocking contact lenses reduce the risk of developing cataracts or other eye disorders. Consult your eye care practitioner for more information.

## PRECAUTIONS

You should be aware of and fully discuss with your eye care practitioner the following safety precautions:

### 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. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Before leaving your eye care practitioner's office, be certain that you are able to remove your lenses promptly or have someone else available to remove them for you.
- Be certain that the fingers or hands are free of foreign materials before touching your lenses, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.

- Always handle your lenses carefully and avoid dropping them.
- Do not touch the lens with your fingernails.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing, and wearing instructions in this booklet and those prescribed by your eye care practitioner.
- Never use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.

### LENS WEARING PRECAUTIONS

- Never wear your lenses beyond the period recommended by your eye care practitioner.
- If the lens sticks (stops moving) on the eye, follow the recommended directions in Care for a Sticking (Non-Moving) Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, you should **immediately** consult your eye care practitioner.
- Avoid, if possible, all harmful or irritating vapors and fumes when wearing lenses.
- If aerosol products are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

### TOPICS TO DISCUSS WITH THE EYE CARE PRACTITIONER

- As with any contact lens, follow-up visits are necessary to ensure the continuing health of the eyes. You should be instructed as to a recommended follow-up schedule.
- You should be advised about wearing lenses during sporting and water-related activities. Exposure to water while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection including, but not limited to, *Acanthamoeba* keratitis.
- Always contact your eye care practitioner before using any medicine in the eyes.
- 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 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. You should be cautioned accordingly.

**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 the use of eye protection equipment or may require that you not wear lenses.

Ask your eye care practitioner whether there are any other wearing restrictions that apply to you. Write those restrictions in the spaces provided below and follow them carefully:

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

You should be aware that the following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when the lens was first placed on the eye
- Abnormal feeling of something in the eye (foreign body, scratched area)
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

If you notice any of the above, **YOU SHOULD:**

- **Immediately remove your lenses.**
- If the discomfort or problem stops, then 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 lens on the eye. If the problem continues, you should **immediately** remove the lenses and consult your eye care practitioner.
- When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. You should **keep the lens off your eye and seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

**PERSONAL CLEANLINESS AND LENS HANDLING**

**1. 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. In particular, 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 come into contact with the lenses and interfere with successful wearing.
- Handle your lenses with your fingertips and be careful to avoid contact with 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.

**2. HANDLING THE LENSES**

- Develop the habit of always working with the same lens first to avoid mix-ups.
- Position the lens on your index finger and examine it to be sure that it is moist, clean, and free of any nicks or tears.
- Should you accidentally place an inside-out lens on your eye, one of the following signs should signal you to remove and replace it correctly:
  - a. Less than usual comfort
  - b. The lens may fold on the eye
  - c. Excessive lens movement on blink
  - d. Blurred vision
- If the lens folds and sticks together: Place the lens in the palm of your hand and wet thoroughly with the recommended rewetting solution. (Refer to the Lens Rewetting Products Available from Bausch + Lomb information below for the solutions available.) Then GENTLY rub the lens between your index finger and palm in a gentle back and forth motion.
- If the lens flattens or drapes across your finger, the lens or your finger may be too wet. To correct this, dry your finger by transferring the lens several times from one index finger to the other, drying the opposite finger each time.

### 3. PLACING THE LENS ON THE EYE

There are other methods of lens placement. If the following methods are difficult for you, your eye care practitioner will provide you with an alternate method.

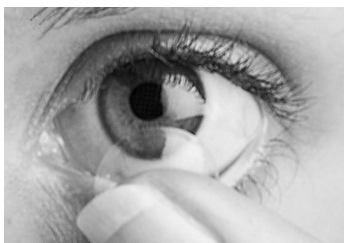
*Note: If after placement of the lens, your vision is blurred, check for the following:*

- The lens is not centered on the eye (see “Centering the Lens” section).
- If the lens is centered, remove the lens (see “Removing the Lens” section) and check for 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).

If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your eye care practitioner.

#### The One Hand Placement Technique

Place the lens on your index finger. With your head up, looking straight ahead, pull down your lower eyelid with the middle finger of your placement hand. Look up steadily at a point above you. Then place the lens on the lower white part of your eye. Remove your index finger and slowly release the lower lid. Look down to position the lens properly. Close your eyes for a moment; the lens will center itself on your eye.



#### The Two Hand Placement Technique

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



If the Lens Feels Uncomfortable, then:

Look in a mirror and gently place a finger on the edge of the contact lens and slowly slide the lens away from your nose while looking in the opposite direction. Then, by blinking, the lens will re-center itself. If the lens still feels uncomfortable, follow the steps described in the section of this booklet entitled “Adverse Reactions (Problems and What to Do)”.

### 4. CENTERING THE LENS

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

- Hold the upper and lower eyelids open with your fingers. Then, while looking in a mirror, gently place a finger on the contact lens and gently slide the lens towards the center of the eye.

Or

- Hold the upper and lower eyelids open with your fingers. Then, while looking in a mirror, move your eye towards the lens to place it on the center of the eye.

## 5. REMOVING THE LENS

Always remove the same lens first.

- a. Wash, rinse, and dry your hands thoroughly.
- b. Always be sure that the lens is in the correct position on your eye before you try to remove it (a simple check of your vision, closing one eye at a time, will tell you if the lens is in the correct position). Look up and slowly pull down your lower lid with the middle finger of your removal hand and place your index finger on the lower edge of the lens. Squeeze the lens lightly between the thumb and index finger and remove it. Avoid sticking the edges of the lens together.
- c. Remove the other lens by following the same procedure.

*Note: If this method of removing your lens is difficult for you, your eye care practitioner will provide you with an alternate method.*

## 6. CARE FOR A STICKING (NON-MOVING) LENS

It is important to the health of your eyes that your contact lenses move freely. If a lens sticks (stops moving), put a few drops of the lubricating or rewetting solution recommended by your eye care practitioner into your eye. In this case, do not use plain water or anything other than the recommended solutions. Do not attempt to remove a lens that is sticking, which could damage your eye. If the lens does not begin to move when you blink after several applications of the solution or drops, contact your eye care practitioner immediately. Do not attempt to remove the lens except on the advice of your eye care practitioner.

## 7. 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.**

## LENS REWETTING PRODUCTS AVAILABLE FROM BAUSCH + LOMB

Bausch + Lomb ReNu MultiPlus® Lubricating and Rewetting Drops

Bausch + Lomb Sensitive Eyes® Drops

## INSTRUCTIONS FOR THE MONOVISION OR MULTIFOCAL WEARER

- You should be aware that as with any type of lens correction, there are advantages and disadvantages to monovision or multifocal contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that is available may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks.
- Some patients have experienced difficulty adapting to monovision contact lens therapy. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your prognosis for successful adaptation.
- You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations, which are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with monovision or multifocal correction if you pass your state driver's license requirements with monovision or multifocal correction.
- Some patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your eye care practitioner having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.
- If you require very sharp near vision during prolonged close work, you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required.
- Some patients require supplemental spectacles to wear over the monovision or multifocal correction to provide the clearest vision for critical tasks. You should discuss this option with your eye care practitioner.
- It is important that you follow your eye care practitioner's suggestions for adaptation to monovision or multifocal contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.
- **The decision to be fit with a monovision or multifocal correction is most appropriately left to the eye care practitioner in conjunction with you, after carefully considering and discussing your needs.**



# PERSONAL WEARING SCHEDULE RECORD

Your eye care practitioner will prescribe your own individual lens wearing schedule and lens replacement schedule. Use the space below to record your schedule and wearing record.

| DAY | DATE | HOURS TO BE WORN | HOURS WORN |
|-----|------|------------------|------------|
| 1   |      |                  |            |
| 2   |      |                  |            |
| 3   |      |                  |            |
| 4   |      |                  |            |
| 5   |      |                  |            |
| 6   |      |                  |            |
| 7   |      |                  |            |
| 8   |      |                  |            |
| 9   |      |                  |            |
| 10  |      |                  |            |
| 11  |      |                  |            |
| 12  |      |                  |            |
| 13  |      |                  |            |
| 14  |      |                  |            |
| 15  |      |                  |            |
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| 17  |      |                  |            |
| 18  |      |                  |            |
| 19  |      |                  |            |
| 20  |      |                  |            |
| 21  |      |                  |            |
| 22  |      |                  |            |
| 23  |      |                  |            |
| 24  |      |                  |            |

# CHECK-UP VISITS

Regular check-up examinations by your eye care practitioner is an important part of wearing contact lenses. It is recommended that you follow your eye care practitioner's directions for follow-up examinations. Keep all appointments for your check-up visits. If you move to a new city, ask your present eye care practitioner to refer you to a contact lens practitioner in your new location. Use the space below to record your appointments.

## VISIT SCHEDULE

|     |      |      |
|-----|------|------|
| 1.  | Date | Time |
| 2.  | Date | Time |
| 3.  | Date | Time |
| 4.  | Date | Time |
| 5.  | Date | Time |
| 6.  | Date | Time |
| 7.  | Date | Time |
| 8.  | Date | Time |
| 9.  | Date | Time |
| 10. | Date | Time |

# EYE CARE PRACTITIONER INFORMATION

Please fill out for ready use

|                    |  |
|--------------------|--|
| Name:              |  |
| Address:           |  |
| Phone:             |  |
| Email Address:     |  |
| Other Information: |  |
















**IMPORTANT:** In the event that you experience any difficulty wearing your lenses or you do not understand the instructions given to you, **DO NOT WAIT** for your next appointment. **CONTACT YOUR EYE CARE PRACTITIONER IMMEDIATELY.**

# GLOSSARY OF MEDICAL TERMS

|                                  |   |
|----------------------------------|---|
| <b>Acute inflammation</b>        | Sudden swelling, redness and pain   |
| <b>Adnexa</b>                    | Tissues surrounding the globe of the eye  |
| <b>Ametropia</b>                 | Abnormal vision requiring correction for proper focus   |
| <b>Anterior chamber</b>          | Internal portion of the eye, between the cornea and iris  |
| <b>Aphakic</b>                   | Lacking a crystalline lens (focusing lens inside the eye)   |
| <b>Astigmatism</b>               | A condition where the cornea is not equally curved in all parts of its surface. It is somewhat oval in shape, causing the visual image to be out of focus (blurred) |
| <b>Cataract</b>                  | Opacity of the crystalline lens (focusing lens inside the eye)  |
| <b>Conjunctiva</b>               | Membrane that lines the eyelids and the white part of the eye   |
| <b>Cornea</b>                    | Clear, front covering of the eye  |
| <b>Corneal ulcer</b>             | A sore or lesion on the cornea, which left untreated could lead to permanent loss of vision   |
| <b>Endothelial polymegathism</b> | Irregular cell size and shape   |
| <b>Epithelial</b>                | Layer of cells on the surface of the cornea   |
| <b>Epithelial microcysts</b>     | A small abnormal structure (cyst) in the front surface of the eye   |
| <b>Hyperopia</b>                 | Farsightedness  |
| <b>Hypoxia</b>                   | Lack of oxygen  |
| <b>Iritis</b>                    | Internal inflammation of the colored part of the eye (iris)   |
| <b>Microbial keratitis</b>       | An infected corneal ulcer   |
| <b>Monovision</b>                | A correction method for presbyopia (loss of reading vision) using contact lenses; one eye is fitted for distance vision, the other for near vision                  |
| <b>Multifocal</b>                | Lenses that contain two or more lens powers to enable viewing at multiple distances   |
| <b>Myopia</b>                    | Nearsightedness   |
| <b>Neovascularization</b>        | Small blood vessels growing into the cornea   |
| <b>Non-aphakic</b>               | Not lacking a crystalline lens  |
| <b>Presbyopia</b>                | Condition in which the eye can no longer focus near objects. It commonly develops in people around the age of 40  |
| <b>Subacute inflammation</b>     | Gradual swelling, redness, and pain   |
| <b>UV (Ultraviolet)</b>          | Light from the sun that can be harmful to the eye   |

# SYMBOL GLOSSARY

Comprehensive guide to symbols that may appear on product labels and cartons.

| Symbol  | Symbol Title  | Symbol Description   | Standard Reference | Title and Designation Number of the Standard  |
|---|---|--|--------------------|---|
|    | Manufacturer  | Indicates the medical device manufacturer  | 5.11               | <b>ISO 15223-1:2021</b><br>Medical device - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements |
|     | Authorized representative in the European Community/European Union      | Indicates the Authorized representative in the European Community/European Union   | 5.12               |   |
|    | Date of manufacture   | Indicates the date when the medical device was manufactured  | 5.13               |   |
|    | Use-by date   | Indicates the date after which the medical device is not to be used  | 5.14               |   |
|    | Batch code  | Indicates the manufacturer's batch code so that the batch or lot can be identified   | 5.15               |   |
|     | Sterilized using steam  | Indicates a medical device that has been sterilized using steam  | 5.2.5              |   |
|    | Do not use if package is damaged and consult instructions for use       | Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information  | 5.2.8              |   |
|     | Single sterile barrier system with protective packaging outside         | Indicates a single sterile barrier system with protective packaging outside  | 5.2.14             |   |
|    | Do not re-use   | Indicates a medical device that is intended for one single use only  | 5.4.2              |   |
|     | Consult instructions for use or consult electronic instructions for use | Indicates the need for the user to consult the instructions for use  | 5.4.3              |   |
|    | Caution   | Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences | 5.4.4              | <b>ISO 8601:2019</b><br>Date and time – Representations for information interchange – Part 1: Basic rules   |
|    | Medical device  | Indicates the item is a medical device   | 5.7.7              |   |
| DIA Ø <sub>r</sub>  | Total diameter  | Indicates total diameter of lens   | N/A                |   |
| BC  | Base curve  | Indicates base curve of lens   | N/A                |   |
| PWR F <sub>v</sub>  | Paraxial back vertex power  | Indicates lens power in diopters   | N/A                |   |
| SPH   | Sphere power  | Indicates spherical power in diopters  | N/A                |   |
| AX  | Cylinder axis   | Indicates axis of cylinder power in degrees  | N/A                |   |
| CYL   | Cylinder power  | Indicates cylindrical power in diopters  | N/A                |   |
| ADD   | Additional power  | Indicates additional power in diopters   | N/A                |   |
| YYYY-MM   | Effective date  | Indicates the date in which the insert revision was made effective   | N/A                |   |
|   | Prescription only (USA)   | Indicates that federal law (U.S.) restricts this device to sale by or on the order of a licensed practitioner  | N/A                | 21 CFR 801.109  |
|   | CE number   | Indicates the CE Conformity Marking and the Notified Body Number   | N/A                | MDR 2017/745, Article 20, 3   |
|  | Green dot   | Indicates paid fee to meet EU packaging directive  | N/A                | 94/62/EC  |