

## Monthly disposable soft contact lenses

**CAUTION**  
 Federal (U.S.A) law restricts this device to sale or on the order of a licensed practitioner.

**IMPORTANT**  
 This package insert is intended for the eye care professional, but should be made available to patients upon request. The eye care professional should provide the patient with appropriate instructions that pertain to the patient's prescribed lenses and recommended wearing schedule. Long term exposure to UV radiation is a part of the risk factors associated with cataracts. Exposure is according to a number of factors for instance environmental conditions (geography, altitude) and personal factors (nature of outdoor activities). UV blocking contact lenses help to resist harmful UV radiation. In any case, clinical studies have not proved that wearing UV blocking contact lenses decrease the risk factor associated with cataracts.

**DESCRIPTION**  
 The non-ionic lens material. It consists of a polymer of 2-Hydroxyethylmethacrylate (2-HEMA) and cross-linked with ethylene glycol dimethacrylate (EGDMA) via UV photo-polymerization. The copolymer consists of 52% Polymacon and 38% water by weight when immersed in buffered saline solution. The lens polymer contains a UV absorbing compound and is available clear or with a blue visually-hiding tint. Color available: "Reseach Blue 15", CFI CFR part 73.3121. The Polymacon name has been adopted by the United States Adopted Names Council (USAN). A benzotriazole UV absorbing monomer is used to block UV radiation.

The handling tint is reactive blue 19, making the lens more visible when handling. The PEGA/VISION contact lens tint may reduce slightly after repeated disinfection. Slight reduction in tint will not affect the safety or performance of the lens.  
 The physical properties are as follows:  
 Refractive index: 1.453      Light Transmittance: 95 % minimum.      Water Content: 38%  
 The Monthly Disposable Soft Contact Lenses is a hemispherical shell of the following dimensions:  

| Type 1 Sphere & Aspheric  | Type 2 Toric   | Type 3 Multi-Focal   |
|---|--|--|
| * Diameter: 13.8-14.5mm (+0.2mm)<br>* Center Thickness:<br>0.08±0.02 mm (e.g., -3.00D)<br>plus lens - varies with power<br>e.g., -3.00D - 0.20mm (+/-0.02)<br>* Base Curve: 8.3-9.0mm (+0.2mm)<br>* Power: +20.00 D - -20.00D | * Diameter: 13.8-14.5mm (+0.2mm)<br>* Center Thickness:<br>0.08±0.02 mm (e.g., -3.00D)<br>plus lens - varies with power<br>e.g., -3.00D - 0.20mm (+/-0.02)<br>* Base Curve: 8.3-9.0mm (+0.2mm)<br>*Power: -20.00 D - -20.00D<br>*Cylinder Power: -0.25 - -10.00D (in 0.25D increment)<br>*Ast: 10° - 18° | * Diameter: 13.8-14.5mm (+0.2mm)<br>* Center Thickness:<br>0.08±0.02 mm (e.g., -3.00D)<br>plus lens - varies with power<br>e.g., -3.00D - 0.20mm (+/-0.02)<br>* Base Curve: 8.3-9.0mm (+0.2mm)<br>* Power: +20.00 D - -20.00D<br>*Add Power: +0.25 - +3.50D Diopter (in 0.25D increment) |

Color: Tin Blue, Black, Brown, Blue, Green, Violet, Gray, Orange, Red, Gold, Pink, Yellow, White and Each Combination

**INDICATION**  
 Monthly Disposable Soft Contact Lenses is indicated for daily wear for vision correction of refractive ametropia in aphakic or not-aphakic persons with non-diseased eyes that are myopic, hyperopic and presbyopia. The lens may be worn by persons who exhibit refractive astigmatism of 2.00 diopters (D) or less where the astigmatism does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D. Eye Care Practitioners may prescribe the lens for their single-use daily disposable wear or frequent/planned replacement wear with cleaning, rinsing, disinfection and scheduled replacement as prescribed by the eye care practitioner. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical (not heat) lens care system only. **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.  
**CONTRAINDICATIONS (REASONS NOT TO USE)**  
 DO NOT USE THE PEGA/VISION 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.  
 • Severe insufficiency of lacrimal secretion (dry eyes).  
 • Corneal hydrops or 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 (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**  
 The following warnings pertain to advice given the patients regarding contact lens wear:  
 • Problems with contact lenses and lens care products could result in serious injury to the eye, such as scarring and ulceration of the cornea resulting in loss of vision. It is essential that patients strictly compliance with the eye care practitioner's direction and all labeling instructions for correct use of lenses and lens care products.  
 • Studies have shown that contact lens wearers who are smokers have a higher risk lens reactions than nonsmokers, especially when lenses are worn overnight or while sleeping.  
 • If a patient experiences eye discomfort, such as foreign body sensation, excessive tearing, vision changes, or redness of the eye or other problems. The patient should immediately remove lenses and promptly contact his or her eye care practitioner.  
 • Monthly lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions are increased when lenses are worn overnight.  
 • Non-compliance with the manufacturer's labeled lens care instruction may put the patient at significant risk of developing a serious eye infection.  
 • The need for strict compliance with the care regimen including cleaning of the lens case, wearing restrictions, wearing schedule, and follow-up visit schedule should be emphasized to the patient.

**HANDLING OF LENSES**  
 Verify that the lens is right side out. The lens should assume a natural, curved, bowl-like shape. If the lens edges tend to point outward, the lens is inside out.  
 Another method is to gently squeeze the lens between the thumb and forefinger. The edges should turn inward. If the lens is inside out, the edges will turn slightly outward/lenses are worn overnight or while sleeping.  
 • If a patient experiences eye discomfort, such as foreign body sensation, excessive tearing, vision changes, or redness of the eye or other problems. The patient should immediately remove lenses and promptly contact his or her eye care practitioner.  
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**PRECAUTIONS**  
 Special Precautions for Eye Care Practitioners:  
 • 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, 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 eye should be carefully monitored by the prescribing eye care practitioner.  
 • Fluorescein, a yellow dye, should not be used while the patient is wearing the lenses, because the lenses will absorb this dye and it may become discolored. When fluorescein is used in eye, flush the eyes with sterile saline solution. Wait at least 10 minutes before reinserting the lenses. If it is not possible to flush the eyes, wait at least 1 hour before wearing the lenses. If inserted too soon, the lenses may absorb remaining fluorescein.  
 • Before leaving the eye care practitioner's office, the patient should be able to promptly remove lenses or should have somebody else available who can remove the lenses for him or her.  
 • Eye Care Professionals should instruct the patient to remove the lenses immediately if the eyes become red or irritated.  
 • Eye care professional should carefully instruct patients about the following care regimen and safety precautions:  
 • Different solutions can't be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.  
 • Never use solutions recommended for conventional hard contact lenses only.  
 • Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection.  
 • Always use fresh, sterile unexpired solutions.  
 • Always follow directions in the package for the use of contact lens solutions.  
 • Sterile unexpired solutions, when used, should be discarded after the time specified in the labeling directions.  
 • Do not use saliva or anything other than the recommended solutions for lubricating or immersing lenses.  
 • Always keep the lenses completely immersed in the recommended storage solution for contact lens when the lenses are not being worn. Prolonged periods of drying can damage lenses. Follow the lens care directions for Care for a Dried Out Lens.  
 • Always wash hands (before moving) on the eye, follow the recommended directions in Care for a Sticking Lens. The lens should move freely on the eye for the contact health of the eye. If non-movement of the lens continues, immediately consult your eye care practitioner.  
 • Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, aerosol products or hair sprays in the eyes or on the lenses. It is best to put on lenses before putting on make-up. Water-base cosmetics are less likely to damage lenses than oil-base products.  
 • Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision or injury to the eye.  
 • Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Information Booklet for the Monthly Disposable Soft Contact Lenses.  
 • 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. Ask your eye care professional about wearing contact lenses during sporting activities.  
 • Some eye makeup products may cause dryness of the eye, increased lens awareness, lens intolerance, blurred vision or visual changes. These include, but are not limited to, antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness. Caution, patients using such medications accordingly and prescribe proper remedial measures.  
 • Oral contraceptive users could develop visual change or change in lens tolerance when using lenses.  
 • Do not use if the sterile blister package is opened or damaged.  
 • Never use 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 increase the chance of eye infections.

**ADVERSE REACTIONS (Problem and What To Do)**  
 The patient 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 eye.  
 • There may be 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).  
 • Feeling of dryness.  
 • Foreign body sensation.  
 If the patient notices any of the above, he or she should be instructed to:  
 • Immediately remove 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 the eye. Place the lens in the storage case and contact the eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, the patient should immediately remove the lenses and consult the eye care practitioner.  
 • If the above symptoms continue after removal of the lens, or upon reinsertion of a lens, or upon insertion of a new lens, the patient should immediately remove the lens and contact his or her eye care practitioner or physician, who must determine the need for examination, treatment or referral without delay. (See Important Treatment Information for Adverse Reactions.) A serious condition such as infection, corneal ulcer, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, epithelial stinging or bacterial conjunctivitis must be managed and treated carefully to avoid more serious eye damage. Additionally, contact lens wear may be associated with ocular changes which require consideration of discontinuation or restriction of wear. These include but are not limited to local or generalized corneal edema, epithelial microcysts, epithelial staining, infiltrates, neovascularization, endothelial polymegathism, tarsal papillary changes, conjunctival irritation or iritis.  
 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 an early infected ulcer are sometimes similar. Accordingly, such epithelial defect, if not treated properly, may develop into an infected ulcer. In order to prevent serious progression of these conditions, a patient 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 the patient is wearing a contact lens on the affected eye when examined, the lens should be removed immediately and the lens and lens care products retained for analysis and culturing. (NOTE: NOT EXTENDED WEAR)

**FITTING**

• The lens may move adequately on the eye for a suitable fit if the fit is judged to be too tight, the patient must be refit into a fitting which provides the criteria of a well-fitted lens.  
 • Fitting techniques for other contact lenses may not be applicable to the fitting of these lenses.  
 • It is strongly recommended that the patient be provided the appropriate Patient Information Booklet available from PEGA/VISION and understands its contents prior to dispensing the lenses.  
 • Copies of Fitting Guides and Patient Information Booklets for PEGA/VISION lenses are available without charge from: www.pegavision.com.tw

## WEARING SCHEDULE

It is recommended that contact lens wearers see their eye care practitioner twice each year or if directed, more frequently.  
 Day 1 There may be a tendency for the NEW daily wear patient to over-wear the lenses initially. Initial daily wearing schedule should be stressed to these patients.  
 The wearing schedule should be determined by the eye care practitioner. The maximum suggested wearing time for the PEGA/VISION contact lens is:

| DAY   | 1 | 2 | 3  | 4  | 5  | 6                |
|-------|---|---|----|----|----|------------------|
| HOURS | 5 | 7 | 10 | 12 | 14 | All waking hours |

Wearing contact lens is not safely during sleep.

## FREQUENT / PLANNED REPLACEMENT

In a planned replacement program, the replacement schedule is determined by the eye care professional based upon the patient's physiological condition. PEGA/VISION recommends the following replacement schedule for these lenses when prescribed in a Planned Replacement Program: (The eye care professional may determine a replacement schedule greater or less than these suggested intervals based upon clinical examination of the patient, professional judgment, and clinical experience with the lenses because individual responses to contact lenses vary)  
 Monthly Disposable Soft Contact Lenses: Replace Every 4 week  
 wearing schedules (NOTE SEE WEARING TIME)

| Daily Wear Contact Lens                | Water Content | Disposable program | UV block | Wear  |
|--|---------------|--------------------|----------|-------|
| Monthly Disposable Soft Contact Lenses | 38%           | 4 weeks            | Yes      | Daily |

## LENS CARE DIRECTIONS

• Daily lenses are discarded upon removal from the eye each day.  
 • Daily Lenses should not be cleaned, rinsed and disinfected on an emergency basis when replacement lenses are not available. (See BASIC INSTRUCTIONS FOR LENS CLEANING, RINSING AND DISINFECTING below.)  
 Planned Replacement:  
 • Patients must adhere to a recommended care regimen. Lenses must be cleaned, rinsed, and disinfected after removal and prior to reinsertion on the eye according to the package inserts and patient instructions provided with the lens care products recommended by the eye care professional. Failure to follow the correct care regimen in accordance with manufacturer's package inserts and patient instructions may contribute to problems and/or result in the development of serious ocular complications as discussed in WARNINGS.  
 Eye care practitioners should review with the patient lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient: General Lens Care (To First Clean and Rinse, Then Disinfect Lenses) Basic Instructions.

## LENS CARE PRODUCT CHART

The following solutions are recommended lens care solution for use with PEGA/VISION Contact Lenses. Eye Care Practitioners should review with the patient lens care directions, including both basic lens care information and specific instruction on the lens care regimen recommended for the patient.  
 Basic Instructions for Lens Cleaning, Rinsing and Disinfection:  
 Care of contact lenses takes very little time to keep your eye health.  
 • Always lenses are discarded. The eye care professional should recommend an appropriate system of lens care and provide the patient with instructions according to the package labeling.  
 • Note: Some solutions may have more than one function, which would be indicated on the label. Read the label on the solution bottle, and follow instructions.  
 • Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.  
 • After cleaning and rinsing, disinfect lens using the system recommended by the manufacturer and/or the eye care practitioner.  
 • After storing lenses, inspect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately after disinfection, you should consult the labeling of the storage solution for information on lens storage.  
 • After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals.  
 • Eye care practitioners may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.  
 • Lenses prescribed in a frequent replacement program should be thrown away after the recommended wearing period prescribed by the practitioner. (See indications)

Many solutions are now multipurpose and can be used to clean, rinse and disinfect as indicated by the instructions and the labeling. To help avoid serious eye injury from contamination:  
 • Always wash, rinse and dry hands before handling the lenses.  
 • Use only fresh sterile solutions recommended for use with soft (hydrophilic) contact lenses. When opened, sterile non-preserved solutions must be discarded after the time specified in the label directions.  
 • Do not use saliva, tap water, homemade saline solution, distilled water, or anything other than a recommended sterile solution indicated for the care of soft lenses.  
 • Do not reuse solutions.  
 • Use fresh solutions for each lens care step. Never add fresh solution to old solution in the lens case.  
 • Always empty and rinse the lens case with fresh sterile rinsing or disinfecting solution and allow to air dry. At the next use of the lens case, fill with fresh sterile solution.  
 • Replace the lens case at regular intervals to help prevent case contamination by microorganisms which can cause eye infection.  
 • Do not alternate or mix lens care systems unless indicated on solution labeling.  
 • Never use a hard (rigid) lens solution unless it is also indicated for use with soft contact lenses. Corneal injury may result if hard (rigid) lens solutions not indicated for use with soft lenses are used in the soft lens care regimen.  
 • Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn to avoid lens dehydration.  
 • Always use fresh unexpired lens care solutions.  
 • Lenses should be cleaned, rinsed, and disinfected each time they are removed. Cleaning and rinsing are necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs.  
 • Always remove, clean, rinse, enzyme and disinfect lenses according to the schedule prescribed by the eye care practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.  
 • Chemical (Not Heat) Disinfection:  
 • Wash and rinse your hands thoroughly BEFORE HANDLING LENS.  
 • After removal of lenses, CLEAN the lens by applying three drops of cleaner to each surface. Then rub the lens between your fingers for 20 seconds.  
 • AFTER CLEANING, thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile rinsing solution for approximately 10 seconds.  
 • Fill contact lens carrying case with the recommended disinfection and storage solution and place lens in the proper cells and soak as recommend in solution labeling.

• Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.  
 • After cleaning and rinsing, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by the lens manufacturer or the eye care practitioner.  
 • When using hydrogen peroxide lens care systems, lenses must be ineffective before wearing. Follow the recommendations on the hydrogen peroxide system labeling.  
 • Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.  
 • Do not heat the disinfection solution and lenses.  
 • Put the lenses in the unopened storage case until ready to put on the eyes.  
 • Caution: Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement on the eye should reduce the potential for irritation.

**Lens Case Cleaning and Maintenance:**  
 Contact lens cases can be a source of bacteria growth. After removing the lens from the case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is reused again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or your eye care practitioner  
 Lens Care Regimen:  
 Patients must adhere to the lens care regimen recommended by their eye care practitioner for the PEGA/VISION contact Lenses. Failure to follow this procedure may result in development of serious ocular infections.  
 (Note: not for daily lenses)  
 Lens Deposits and Use of Enzymatic Cleaning Procedure:  
 Enzyme cleaning may be recommended by the eye care practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the health of the patient's lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.  
 Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.  
 Care for A Dried Out (Dehydrated) or Dry Lens:  
 If a soft, hydrophilic contact lens is exposed to air while off the eye, it may become dry and brittle and need to be rehydrated. If the lens is adhering to a surface, such as a counter top, apply saline or rinsing solution before handling. To re-hydrate the lens:  
 • Handle the lens carefully.  
 • Place the lens in its storage case and immerse the lens in a recommended rinsing and storing solution for at least two hour until it returns to a soft state.  
 • Clean and disinfect the rehydrated lens using a recommended lens care system.  
 • If after immersion, the lens does not become soft, the lens should not be used until examined by the eye care practitioner.  
 Warning: If disposable lenses dry out completely, please discard immediately.  
 Care for A Sticking (Nonmoving) Lens:  
 If the lens sticks (cannot be moved), you should be instructed to use a lubricating or rewetting solution in your eye. You should apply 3 to 4 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 15 minutes, you should IMMEDIATELY consult your eye care practitioner.  
 Storage:  
 • All lenses that have been opened must be disinfected after each fitting and at least once each week. Unopened lenses are sterile and need not be disinfected until the blister pack seal has been broken.  
 • The PEGA/VISION contact lens must be stored only in the recommended solution.  
 • Always use fresh sterile solution completely immersed in a recommended disinfecting/conditioning solution when the lenses are not being worn.  
 • If the lens dehydrates reference the above section on care for a dried out (dehydrated) OR dry lens.  
 • Storage and transport of product is in room temperature.  
 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:  
**FLY EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVE LENSES PROMPTLY. CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**  
**HOW SUPPLIED**  
 Each PEGA/VISION Contact Lens is marked with the manufacturing lot number of the lens, the base curve, sphere power, cylinder power, axis, diameter, and expiration date on the container.

PEGA/VISION Corp. 2F-1 No.5, Shing Yeh St., Guishan Dist., Taoyuan City 333, Taiwan

Malaysia Authorised Representative:  
 Qualek Consulting Sdn. Bhd. Level 2B, PJ Exchange, No.16A, Persiaran Barat, 46050 Petaling Jaya, Selangor, Malaysia.  
 qualek@qualekcs.com

| SYMBOL | DESCRIPTION  | SYMBOL | DESCRIPTION   |
|--------|--|--------|---|
|        | • Product certification<br>• Notify body number: 2460            |        | • See Instruction Leaflet   |
|        | • Batch code   |        | CAUTION: Federal law restricts this device to sale by or on the order of a licensed practitioner. |
|        | • Use by:<br>• Expressed as:<br>for CCYY-MM-DD YYYY-MM           |        | • Base Curve (product property)   |
|        | • UV-Blocking<br>(The mark is showing functional of UV blocking) |        | • Diameter (product property)   |
|        | • Manufacturer   |        | • Cylinder Power  |
|        | • Diopter (Lens Power)(product property)                         |        | • ADD   |
|        | • Axis   |        |   |

## Kanta sentuh lembut pakai buang bulanan

## (PERINGATAN)

Undang-undang (A.S) persekutuan mengehakdan penjualan peranti ini atau mengikut pesanan daripada pengamal yang berlesen.

Sisipan bungkusan ini adalah untuk pakar pengajanan mata, tetapi hendaklah boleh didapati oleh pesakit atas permintaan. Pakar pengajanan mata hendaklah memberikan pesakit arahan yang sewajarnya yang berkenaan dengan kanta pesakit yang dipreskripsikan dan dalam keadaan yang disyorkan. Pendedahan jangka panjang kepada pancaran UV adalah sebahagian daripada faktor risiko yang berkaitan dengan katarak. Pendedahan adalah menuntut

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