OPTIK K&R Inc.
Toronto, Ontario M1P 3A6
Canada

PACKAGE INSERT

RP Toric 38[tm] (polymacon) Hydrophilic Contact Lens

IMPORTANT: Please read carefully and keep this information for future use. This package insert is intended for the eyecare practitioner, but should be made available to patients upon request. The eyecare practitioner should provide the patient instructions that pertain to the patient's prescribed lens.

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION

PRODUCT DESCRIPTION

The **RP TORIC 38[tm] (polymacon) Hydrophilic Contact Lenses** are available as spherical (single power) lenses. The lens material (polymacon) is a copolymer of 2-hydroxyethyl methacrylate (HEMA). When hydrated, the lenses consists of 62% HEMA and 38% water by weight when immersed in normal saline. An Ultraviolet inhibitor is infused in the matrix of the polymer. The **RP TORIC 38[tm] (polymacon) Hydrophilic Contact Lenses** are a hemispherical flexible shell which covers the cornea and a portion of the adjacent sclera. For dimensions refer to LENS PARAMETERS AVAILABLE.

LENS PARAMETERS AVAILABLE

- Chord Diameter: 14.0, 14.5 mm
- Center Thickness: 0.06 mm to 0.58mm
- Base Curve: 8.1, 8.4, 8. 7, 9.0 mm
- Power Range: sphere: +20.00 Diopters to -20.00 Diopters in 0.25D increments
  cylinder: -0.25 to -11.00D in 0.25D increments
  axis: 1° to 180° in 1° increments
- Color: clear or with blue locator tint

LENS PROPERTIES AVAILABLE

The physical/optical properties of the lens are:

- Refractive Index: 1.43
- Light Transmittance clear 97% minimum
- Light Transmittance blue 85% minimum
- UV blocking 82% UVA (316mm to 380nm), 97% UVB (280nm to 315nm)
- Surface Character: hydrophilic
- Water [Content] [Absorption]: 38%
- Oxygen Permeability (Dk)*: 9.0 x 10^{-11} (cm^2/sec) (ml O_2 /ml x mm Hg) at 35°C

*[Fatt Method for determination of oxygen permeability]

ACTIONS

In its hydrated state, the **RP TORIC 38[tm] (polymacon) Hydrophilic Contact Lenses** act as a refracting medium to focus light rays on the retina.

INDICATIONS (USES)

The **RP TORIC 38[tm] (polymacon) Hydrophilic Contact Lenses** are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) with non-diseased eyes that may exhibit astigmatism up to 11.00 diopters. The lenses may be disinfected using a heat, or chemical disinfection system. Eyecare practitioners may prescribe the lens for daily wear and/or frequent replacement. When prescribed for a Frequent Replacement Program, the lenses may be disinfected using heat, or chemical disinfection systems.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the **RP TORIC 38[tm] (polymacon) Hydrophilic Contact Lenses** when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Ocular irritation due to allergic reactions, which may be caused by use of contact lens solutions (i.e. rewetting drops) that contain chemicals or preservatives (such as mercury or Thimerosal) which some people may develop an allergic response.
- Any active corneal infection (bacterial, fungal, or viral)
- The use of any medication that is contraindicated or interferes with contact lens wear, including eye medication
- Patient history of recurring eye or eyelid infections, adverse effects associated with contact lens wear.
- If eyes become red or irritated.

WARNINGS

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that patients follow their eye care professional's directions and all labeling instructions for proper use of their 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 patients should be instructed not to wear their lenses while sleeping. Clinical study results[1] have shown that the risk of serious adverse reactions including ulcerative keratitis is nine times greater for daily wear users who wear their lenses overnight (outside the approved indication) compared to those who do not wear them overnight. Studies[1] have also shown that contact lens wearers who smoke have a higher incidence of adverse reactions (estimated 3 to 8 times greater risk of suffering ulcerative keratitis) than among those who are non-smokers. If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact his or her eye care practitioner. It is recommended that contact lens wearers see their eye care professional regularly as directed.

PRECAUTIONS

Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configuration, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameter, the eyecare 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 the eye should be carefully monitored by the prescribing eyecare practitioner.

- Patients who wear aspheric contact lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use; and the patient should wait at least 1 hour before replacing the lenses.
- Before leaving the eyecare practitioner's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.

Eye care practitioners should carefully instruct patients about the following care regimen and safety precautions:

- Different solutions cannot always 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 unexpired lens care solution.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Sterile unpreserved 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 wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying may damage the lenses. Follow the lens care directions for CARE FOR A DRIED OUT (DEHYDRATED) LENS if lens surface does become dried out.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on CARE FOR A STICKING LENS. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her eyecare practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorant, or sprays in the eyes or on the lenses. It is best to put on lenses putting on makeup. 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 and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for the **RP TORIC 38[tm] (polymacon) Hydrophilic Contact Lenses** and those prescribed by the eyecare practitioner.
- Never wear lenses beyond the period recommended by the eyewear practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eyecare practitioner about wearing lenses during water activities and other sports.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Always contact eyecare practitioner before using any medication in the eyes.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to recommended follow-up schedule.
- **RP TORIC 38[tm] (polymacon) Hydrophilic Contact Lenses** when prescribed in a Frequent Replacement Program are intended to be disposed of at the end of the prescribed period (1 week, 2 weeks, 1 month, etc.). Therefore, it is important to always have available a pair of replacement lenses.

ADVERSE EFFECTS

The patient should be informed that the following problems may occur:

* Eye pain
* Eyes sting, burn, or itching (irritation)
* Comfort is less than when lens was first placed on eye
* Abnormal feeling of something in the eye (foreign body, scratched area)
* Excessive watering (tearing) or 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 the patient notices any of the above, he or she should be instructed to:

* **Immediately remove lens(es).**
* **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 eyecare practitioner. If the lens has the 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 LENS(ES) AND CONTACT THEIR EYE CARE PROFESSIONAL AT ONCE.**

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to keep lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

REPORTING AF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing the **RP TORIC 38[tm] (polymacon) Hydrophilic Contact Lenses** should be reported by **licensed eye care practitioners** to:

OPTIK K&R Inc.
425 Midwest Road Toronto, Ontario M1P 3A6 Canada

Tel: (800) 465-0048 or (416) 915-1550 Fax: (888) 243-6529 or (416) 915-1551
Email: info@KandR.com

SELECTION OF PATIENTS

RP TORIC 38[tm] (polymacon) Hydrophilic Contact Lens is intended for the daily wear patient who may require the correction of visual acuity for myopia, hyperopia or astigmatism up to 11.00 diopters. **RP TORIC 38[tm] (polymacon) Hydrophilic Contact Lens** are suitable for patients who have never worn contact lenses, for current PMMA wearers, for patients wanting to upgrade their current soft contact lenses, as well as for some patients who are unsuccessful with rigid gas permeable lenses.

FITTING

Conventional methods of fitting contact lenses do not apply to the **RP TORIC 38tm (polymacon) Hydrophilic Contact Lens**. For a detailed description of the fitting techniques, refer to the **RP TORIC 38tm (polymacon) Hydrophilic Contact Lens** Fitting and Information Guide, copies of which are available from our Web site at :

www.KandR.com

Or by mail or fax at:

OPTIK K&R Inc.
425 Midwest Road
Toronto, Ontario M1P 3A6 Canada

Fax: (888) 243-6529 Email: info@KandR.com

WEARING SCHEDULE:

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY THE EYECARE PRACTITIONER. Patients tend to overwear the lenses initially. The eyecare practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eyecare practitioner, are also extremely important.

The **RP TORIC 38tm (polymacon) Hydrophilic Contact Lens** are indicated for daily wear. The maximum suggested wearing time for the lenses is:

DAY	HOURS	DAY	HOURS	
1	[4]		6	[9]
2	[5]		7	[10]
3	[6]		8	[11]
4	[7]		9	[12]
5	[8]		10 and after	all waking hours

Studies have not been completed to show that the **RP TORIC 38tm (polymacon) Hydrophilic Contact Lenses** are safe to wear during sleep.

LENS CARE DIRECTIONS

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:

- Always wash, rinse, and dry hands before handling contact lenses.
- Always check the expiry date on the lens care solutions.
- Use the recommended system of lens care, either heat or chemical (not heat) and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Do not alternate or mix lens care system unless indicated on solution labeling.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- 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, and disinfect lenses daily. Enzyme lenses according to a schedule prescribed by your eyecare practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.
- The eyecare practitioner should recommend a care system that is appropriate for the **RP TORIC 38tm (polymacon) Hydrophilic Contact Lenses**.Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.
- Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.
- Clean one lens first (always the same lens first 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, disinfect lenses using the system recommended by the eyecare practitioner.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. Lenses stored longer than 12 hours may require cleaning, rinsing and disinfection again before use. The patient should consult the package insert or the eyecare practitioner for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with rinsing solution; then allow the lens case to air dry. When the case is used again, refill it with fresh storage solution. Replace lens case at regular intervals.
- Eyecare practitioners may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they mare being worn to make them more comfortable.

Heat or Ultraviolet Disinfection (no chemical)

- After cleaning and thoroughly rinsing contact lenses with recommended solutions, prepare the empty lens storage case. To keep the lenses wet during disinfection, use the solution that is recommended by the lens manufacturer and/or the eye care practitioner.
- Wet the lens chambers (sections) with fresh saline solution.
- Put each lens into its correct chamber.
- Fill the chambers of the case to the line with fresh saline solution. Completely cover the lenses.
- Tightly close the top on each chamber of the lens storage case
- Put the lens storage case into the disinfection unit and follow the disinfection unit manufacturer's directions for operating the unit (turning the unit on, assuring that it works, and leaving it on for a sufficient time to disinfect the lenses).ion of the lenses, no rinsing is necessary unless the eye care practitioner recommends rinsing.

Chemical (Not Heat) Disinfection

- Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- After cleaning, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended the eye care practitioner.
- **DO NOT USE hydrogen peroxide lens care system. Peroxides may cause the lens to yellow.**
- 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.
- Leave the lenses in the unopened storage case until ready to put on the eyes.

CAUTIONS: 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 DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE

The eye care practitioner may recommend enzyme cleaning. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for well-being 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.

LENS CASE CLEANING AND MAINTENANCE

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed with rinsing solution, and allowed to air dry. Lens cases should be replaced at regular intervals.

CARE FOR A DRIED OUT (DEHYDRATED) LENS

If your **RP TORIC 38tm (polymacon) Hydrophilic Contact Lenses** are off your eye and exposed to air for twenty minutes or longer, it will become dry and brittle. To rewet the lens:

- Place the lens in its storage case and soak the lens in recommended rinsing and storage solution for at least one hour or until the lens again feels soft and pliable.
- Clean, rinse and disinfect the rewetted lens using the lens care system recommended by your eye care practitioner.
- If after soaking, the lens does not become soft or the surface remains dry, DO NOT PLACE THE LENS IN YOUR EYE. Contact your eye care practitioner.

CARE FOR A STICKING LENS

If the lens sticks (stop moving), the patient should be instructed to apply 1 to 2 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 no movement of the lens continues the patient should immediately consult the eyecare practitioner.

IN OFFICE CARE REGIMEN FOR TRIAL LENSES

Eyecare practitioners should educate contact lens technicians concerning proper care of trial lenses.

Each contact lens is shipped sterile in a vial with sterile saline solution. Hands should be thoroughly washed and rinse and dried with a lint free towel prior to handling a lens. In order to insure sterility, the vial should not be opened until immediately prior to use. Lenses should be surface cleaned and disinfected prior to re-using in a diagnostic procedure or before dispensing to a patient.

Follow the disinfection procedures described above for proper disinfection of office trial lenses.

FREQUENT REPLACEMENT PROGRAM

For complete information concerning the Frequent Replacement Program, please refer to the Professional Fitting and Information Guide for the **RP TORIC 38tm (polymacon) Hydrophilic Contact Lenses.**

EMERGENCIES:

The patient should be informed that if chemicals of any kind (household products, gardening solution, laboratory chemicals, etc.) are splashed into the eyes, the patient should: **FLUSH EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVE LENSES PROMPTLY. CONTACT THE EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

HOW SUPPLIED

Each lens is supplied sterile in glass vials containing isotonic saline solution. The glass vial is labeled with the base curve, diopter power, axis, diameter, lot number, and expiration date of the product

1 New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783