PACKAGE INSERT

OPTIMUM GP (roflufocon A, C, D & E) Rigid Gas Permeable (RGP) CONTACT LENSES FOR DAILY WEAR

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER

IMPORTANT

Please read carefully and keep this information for future use. This package insert is intended for the eye care practitioner, but should be made available to the patient upon request. The eye care practitioner should provide this package insert along with the prescribed contact lens package insert to the patient to insure proper use.

DESCRIPTION OF LENSES

The OPTIMUM GP series of contact lenses are fabricated from the hydrophilic contact lens materials (roflufocon A), (roflufocon C), (roflufocon D), & (roflufocon E). When placed on the cornea, the OPTIMUM GP rigid gas permeable contact lenses act as a refracting medium to focus light rays upon the retina.

The OPTIMUM GP Contact Lens for Daily Wear are available as matte clear contact lenses with sphercial, biconal, multifocal or toric anterior and/or posterior designs in clear and tinted versions. The OPTIMUM GP contact lenses may be packaged and shipped wet in the Optimum Cleansing, Disinfecting and Storage Solution. The packaging is a sterile solution containing 0.5% sodium edetate. The lenses are packaged in a 25-year-old person as described in Wexler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, Figure 5.

NOTE: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on the amount of time spent outdoors and on the type or quality of sunglasses worn. UV-blocking contact lenses help reduce the risk of developing cataracts or other eye disorders. Consult your eyecare practitioner for more information.

INDICATIONS

The OPTIMUM GP (roflufocon A, C, D & E) Rigid Gas Permeable Contact Lens is indicated for daily wear for the correction of visual acuity in aphatic and non-aphatic persons with non-diseased eyes with myopia or hyperopia. The lens may be disinfected with a chemical disinfection solution and the eye care practitioner should consider all the characteristics of the lens that can affect lens performance and ocular health. Prevention of UV radiation. However, the clinical studies may not have included all design configurations, or lens parameters available in the lens material.

PRECAUTIONS

Special Precautions for the eye care practitioner and/or physician:

- Impacts lens contact packaging for shipping when lenses are wet shipped in Optimum by Lobob cleaning, disinfecting and storage solution. If the packaging is damaged or leaking, throw away damaged packaging and replace with a new contact lens container and refill with new cleaning, disinfection and storage solution.
- Preparing to dispense, it is important to THOROUGHLY RINSE all OPTIMUM GP Cleaning, Disinfecting and Storage Solution every 30 days from initial manufacture date. The new Optimum GP solution shall be Fresh, Sterile, Useable from a new unopened bottle.
- Clinical studies have demonstrated that contact lenses made from (roflufocon A, C, D & E) are safe and effective for their intended use. However, the clinical studies may not have included all lens parameters that are presently available in this lens material. 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.
- The potential impact of these factors on the patient’s ocular health must be considered against the patient’s need for refractive correction. For example, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

CONTRAINDICATIONS (REASONS NOT TO USE)

- *Patients unable to follow lens care regimen or unable to obtain assistance to do so.
- *Aphakic patients should not be fitted with OPTIMUM GP (RGP) Contact Lenses until the determination is made that the eye has healed completely.
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- *Allergy to any active ingredient in Optimum by Lobob cleaning, disinfecting and storage solution.
- *Any active corneal infection (bacterial, fungal, or viral).
- *If eyes become red or irritated.
- *Eye care practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- *Stays have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than non-smokers.
- *Eye care practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- *Thoroughly rinse the OPTIMUM GP lenses with fresh, sterile saline or rinsing solution prior to insertion.
- *Before leaving the eye care practitioner’s office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lens for him/her.
- *Eye care practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.

WARNINGS

- *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.
- *Aphatic patients should not be fitted with OPTIMUM GP (RGP) Contact Lenses until the determination is made that the eye has healed completely.
- *Severe insufficient of lacrimal secretion (dry eyes).
- *Corneal hyposthesia (reduced corneal sensitivity), if not-aphatic.
- *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.
- *Allegry to any ingredient, such as mercury or thimerosal, in a solution which is to be used for care for OPTIMUM GP (RGP) Contact Lenses.
- *Patients unable to follow lens care regimen or unable to obtain assistance to do so.
- *Any active corneal infection (bacterial, fungal, or viral).
- *If eyes become red or irritated.

Optimum GP Contact Lens for Daily Wear is a rigid gas permeable methacrylate copolymer of bis(methacryloxypropyl)-1,1,3,3,6,6,8,8-octafluoro-3,3,6,6,8,8-hexahydrobenzonitrile. The UV blocking contact lenses help reduce the risk of developing cataracts or other eye disorders. Consult your eyecare practitioner for more information.

D & E) Rigid Gas Permeable Contact Lens, – 3.00 D & 6.00 mm thick, to that of a cornea and crystalline lens. Data was obtained from measurements taken through the central 3-5 mm portion of the thinnest marketed version of the UV lens.

Cornea – Human cornea from a 24-year-old person as described in Lerman, S., Radiant Energy and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, Figure 5.

NOTE: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on the amount of time spent outdoors and on the type or quality of sunglasses worn. UV-blocking contact lenses help reduce the risk of developing cataracts or other eye disorders. Consult your eyecare practitioner for more information.

INDICATIONS

The OPTIMUM GP (roflufocon A) Rigid Gas Permeable Contact Lens is indicated for daily wear for the correction of visual acuity in aphatic and non-aphatic persons with non-diseased eyes with myopia or hyperopia. The lens may be disinfected with a chemical disinfection solution. The optical thickness, and refractive astigmatism not exceeding 10.00 diopters. The lens may be disinfected with a chemical disinfection solution and the eye care practitioner should consider all characteristics of the lens that can affect lens performance and ocular health.

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WARNING

UV-blocking contact lenses are NOT substitutes for protective UV-blocking eyewear such as UV-blocking sunglasses, hats, etc. They do not block all the UV rays reaching the eye and surrounding area. You should continue to use UV-blocking eyewear as directed.

The following graph compares the UV transmittance profile of the OPTIMUM GP (roflufocon A, C, D & E) Rigid Gas Permeable Contact Lens, – 3.00 D & 6.00 mm thick, to that of a cornea and crystalline lens. Data was obtained from measurements taken through the central 3-5 mm portion of the thinnest marketed version of the UV lens.

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Cornea – Human cornea from a 24-year-old person as described in Lerman, S., Radiant Energy and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, Figure 5.
**WEARING SCHEDULE**

The wearing and replacement schedules should be determined by the Eye Care Practitioner. Patients tend to wear the lenses initially. The eye care practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as directed by the eye care practitioner, should be scheduled.

The maximum suggested wearing schedule for the OPTIMUM GP (RGP) Contact Lenses is reflected below:

| DAY HOURS | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11-12 | 13-15 | 16-18 | 19-21 | 22-24 |
|-----------|---|---|---|---|---|---|---|---|---|----|--------|------|-------|-------|-------|-------|

**STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE OPTIMUM GP (RGP) CONTACT LENS IS SAFE TO WEAR DURING SLEEP.**

WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER.

**LENSES 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.

- **Basic Instructions:**
  - Care of contact lenses takes very little time and involves three essential steps: CLEANING, RINSING AND DISINFECTION. Each step in itself is important, and one step is not to be replaced by the other. Always wash, rinse and dry hands before handling contact lenses. Always use FRESH, STERILE UNEXPired lens care solutions. Use the recommended chemical (not heat) lens care systems. 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 SYSTEMS UNLESS INDICATED ON 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 lenses.
  - Disinfecting is necessary to destroy harmful germs. The lens case must be emptied and refilled with fresh, sterile recommended storage and disinfection solution prior to disinfecting the lenses.
  - Eye care practitioners should recommend a lubricating/rewetting solution, which can be used to rewet (lubricate) lenses while they are being worn to make them more comfortable.

**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.

- **Specific Instructions for Use and Warnings:**
  - Soaking and Storing the Lenses
    - Use only fresh multi-purpose (contact lens disinfecting) solution each time the lenses are soaked (stored).
    - **WARNING:** Do not re-use or “top off” old solution left in the lens case since solution reuse reduces effective lens cleaning and disinfection and could lead to severe infection, vision loss or blindness.

- **Rub and Rinse Time**
  - **Rub and rinse the lenses according to the recommended lens rubbing and rinsing times in the labeling of the multi-purpose solution to adequately disinfect the lenses.

- **Clean**
  - Empty and clean contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/contact lens cleaner. Never use water. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without any additional cleaning methods. If air drying, be sure that no residual solution remains in the case before allowing it to air dry.
  - Replace the lens case according to the directions given by the eye care professional or the labeling that came with the case. Contact lens cases can be a source of bacterial growth.

- **WARNING:**
  - Do not store the lenses or rinse the lens case with water or any non-sterile solution. Only use fresh multi-purpose solution to prevent contaminating the lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

- **Water Activity**
  - **Instruction for Use:**
    - Do not expose the contact lenses to water while wearing them.

- **WARNING:**
  - Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If the lenses have been submerged in water when swimming in pools, lakes or oceans, the patient should discard them and replace them with fresh, sterile, unopened contact lenses. Eye care practitioners are encouraged to recommend this procedure (professional) for recommendations about using the lenses during any activity involving water.
LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE

The eyecare 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 the 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 daily cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

SYSTEM PROCESS

<table>
<thead>
<tr>
<th>Daily Cleaning</th>
<th>Chemical (not heat)</th>
<th>Disinfection System</th>
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<tr>
<td>Cleaning, Disinfecting and Soaking</td>
<td>Lobob OPTIMUM GP extra strength cleaner</td>
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<tr>
<td>Wetting &amp; Lubricating</td>
<td>Lobob OPTIMUM C/D/S</td>
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<tr>
<td>Wetting &amp; Rewetting</td>
<td>Lobob OPTIMUM GP wetting and rewetting</td>
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RECOMMENDED SOLUTIONS

OPTIMUM GP lenses should be disinfected using only a chemical (not heat) disinfection system. The following lens care systems are recommended (or other lens care systems as recommended by your eye care practitioner).

Product List -
1. OPTIMUM GP Daily Cleaner, OPTIMUM GP WRW (wetting & rewetting solution), OPTIMUM GP C/D/S (cleaning, disinfecting, soaking solution) by Lobob Laboratories.

PURCHASE SOLUTIONS ON THE INTERNET AT: WWW.LOBOBLABS.COM

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:

FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED:

Each lens is supplied non-sterile in an individual plastic case. The OPTIMUM GP contact lens may be packaged and shipped wet in the Optimum Cleaning, Disinfecting and Storage (CDS) GP solution.

The product is a sterile solution containing lauryl sulfate salt of imidazoline octylphenoxypolyethoxyethanol, and preserved with benzyl alcohol (0.3%) and disodium edetate (0.5%).

The case, packing slip and invoice are marked with the base curve, dioptic power, diameter, center thickness, color, lot number and the initial packaging date.

Additional Package Inserts are available from: www.synergeyes.com

REPORTING OF ADVERSE REACTIONS:

Practitioners should report any adverse reactions within 5 days to SynergEyes Inc.
SynergEyes Inc.
5927 Priestly Drive, Suite 210
Carlsbad CA 92008

USA / Canada Contact Information:
E-Mail: customerservice@synergeyes.com
Telephone: 1-877-733-2012 option 1
Fax: 1-877-329-2012

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Contact Lens material Manufactured By:
ContacMax Ltd.
Carlton House
Shire Hill
Saffron Walden
Essex CB11 3AU
United Kingdom