

PARAGON RG-4™

CONTACT LENSES
FOR
CORNEAL RESHAPING
HAVE BEEN FITTED

Instructions for Wearers of PARAGON RG-4™ Contact Lenses for Corneal Reshaping



Instructions for Wearers of

PARAGON RG-4™ (paflucocon D)

Contact Lenses for Contact Lens Corneal Reshaping

Patient Name: _____

Prescribed Lens: _____

Dr. _____

Address: _____

Phone: _____

CAUTIONS: Federal (US) law restricts this device to sale by, or on the order of a licensed practitioner.

Contact lenses for Corneal Reshaping should be fitted only by a trained and certified contact lens fitter. Nonsterile. Clean and condition lenses prior to use.

The lens is shipped dry; or, wet shipped in Boston SIMPLUS® solution.* This solution contains poloxamine, hydroxyalkylphosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, Glucam and preserved with chlorhexidine gluconate (0.003%), polyaminopropyl biguanide (0.0005%). The case, packing slip or invoice is marked with the base curve radius, dioptric power, diameter, center thickness, serial number, fill date and the color of the lens.

*Boston SIMPLUS® is a registered trademark of Bausch & Lomb.

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PRECAUTIONS

General

Clinical studies have demonstrated that Paragon RG-4™ contact lenses manufactured from Paragon HDS® 100 are safe and effective for their intended use. However, due to the small number of patients enrolled in the clinical investigation of lenses, all refractive powers, design configurations, and lens parameters available in the lens materials were not evaluated in significant numbers. This is especially true for adolescent subjects in this investigation. 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 your ocular health; including, oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on your ocular health must be carefully weighed against the your need for refractive reduction; therefore, the your continuing ocular health and lens performance on your eye should be carefully monitored by your eye care practitioner. Corneal edema is more prevalent when the lens is used in high altitudes.

The safety and effectiveness of the Paragon RG-4™ design in the overnight wear modality was established partially on the basis of the experience with the Paragon CRT® 100 design in the same lens materials. Therefore, some differences in efficacy may be observed.

Each Paragon RG-4™ lens is supplied nonsterile in an individual plastic case. The lens is shipped dry; or, wet shipped in Boston SIMPLUS® solution.* This solution contains poloxamine, hydroxyalkylphosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, Glucam and preserved with chlorhexidine gluconate (0.003%), polyaminopropyl biguanide (0.0005%). If the patient has experienced a prior history of allergy to any of these ingredients, remove the lens from the solution and soak the lens 24 hours in sterile unpreserved saline prior to cleaning, disinfecting and dispensing.

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Never reuse the solution. You may store the lens in the unopened container until ready to dispense, up to a maximum of twenty-five (25) days from the Ship Date (see Packing Slip). When a lens has been stored for 25 days in its original packaging solution, it should be cleaned and disinfected with an FDA approved product and placed into inventory as you presently do with any other RGP lens held in your office. Follow the directions on the selected disinfecting solution regarding prolonged storage.

Patient

You should be aware of the following precautions.

Solution Precautions

- Different solutions cannot always be used together and not all solutions are safe for use with all lenses. Use only recommended solutions with your Paragon RG-4™ contact lenses.
- Do not heat the wetting/soaking solution and lenses.
- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts of the contact lens solutions used.
- Use only a chemical lens care system. Use of a heat (thermal) lens care system can cause damage by warping your contact lenses.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva, tap water 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).

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-base cosmetics are less likely to damage lenses than oil-base products.
- Be certain that your fingers or hands are free of foreign material before touching your contact lenses, 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 this booklet and those prescribed by your eye care practitioner.
- Always handle your lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour your lens into your hand.
- Do not touch the lens with your fingernails.
- To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers. Patients should follow the complete recommended lens rubbing and rinsing times in the product labeling to adequately disinfect their lenses and reduce the risk of contact lens contamination. Reduced rubbing or rinsing times may not adequately clean their lenses.

Lens Wearing Precautions

- CAUTION: Clean and condition lenses prior to use. Lenses come non-sterile.
- If the lens sticks (stops moving) on your eye, follow the recommended directions on “Care for a Sticking (Nonmoving) Lens” in this patient information booklet. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, you should immediately consult your eye care practitioner.
- Never wear your contact lenses beyond the period recommended by your eye care practitioner.
- Avoid, if possible, all harmful or irritating vapors and fumes when wearing lenses.
- If aerosol products such as sprays are used while wearing lenses, exercise caution and keep your eyes closed until the spray has settled.

Lens Case Precautions

- Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, patients should fill their lens case with fresh solution every time they store their lenses and never re-use solution. They should discard their solution immediately after their lenses have been removed from the case. They should not store their lenses in or rinse their lens case with tap water, bottled water or any non-sterile solution.
- Patients should clean and rinse their lens case between uses as recommended by their eye care practitioner.
- Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or eye care practitioner.

Discuss these topics with your eye care practitioner

- Wear of contact lenses during sporting activities
- Use of any medication in your eyes
- Importance of adhering to the recommended follow-up schedule to assure the continuing health of your eyes
- Informing your doctor (health care practitioner) about being a contact lens wearer
- Informing your employer of being a contact lens wearer; some jobs may require the use of eye protection equipment or may require that you not wear contact lenses during work hours.

ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO)

You should be informed that the following problems may occur.

- Eyes stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when lens was first placed on eye
- Feeling of something in the eye such as a foreign body or 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 these conditions: **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. Place the lens in the storage case and contact your eye care practitioner. If the lens has dirt, an eyelash, or other foreign objects on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse and disinfect the lens; then reinsert it. If the problem continues, you should **IMMEDIATELY** remove the contact lenses and consult your eye care practitioner.

When any of the above problems occurs, a serious condition such as infection, corneal ulcer neovascularization, iritis, persistent stromal edema or GPC (giant papillary conjunctivitis) may be present. You should keep the lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage, including corneal scarring, opacification, blindness or loss of eye.

PERSONAL CLEANLINESS AND LENS HANDLING

Preparing the Lens For Wearing

- It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substance 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.
- To avoid damaging your lenses, handle them 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.

Handling the Lens

Develop the habit of always working with the same lens first to avoid mix-ups. Remove the lens from its storage case and examine it to be sure that it is moist, clean, and free of any nicks and cracks.

Placing the Lens on the Eye

Work over a table, upon which is placed a clean towel. Do not place lenses on the eye while working over a sink. For the right eye:

- Wet your right index finger with a drop of conditioning solution and place the contact lens front side down on our right index finger.
- Place the second finger of the left hand on the middle of the upper lid and press firmly upward.
- Place the second finger of the right hand on the lower lid and press firmly downward.
- Stare into a mirror as though looking through the second finger holding the contact lens. You will later learn to do this without a mirror.
- Slowly move the hand to advance the forefinger with the contact lens towards the cornea until the lens touches the cornea and release the lids.
- Release the lid and close the eye for a few seconds.

Repeat procedure for the left eye.

There are other methods of lens placement. If this method is 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”, next section in this booklet).
- 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.

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

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 may also occur during placement and removal of the lenses if the correct techniques are not performed properly. To center a lens follow this procedure.

- First locate the lens by pulling away the lids.
- After the lens is found, gently press on the lid over the lens while looking away from the direction of the lens.
- Next look back towards the lens.

Removing the Lens

- Always remove the same lens first.
- Wash, rinse, and dry your hands thoroughly.
- Work over a table with a clean towel. Do not remove lenses over a sink.
- Place the right index finger at the outer corner of the eye.
- Place the left hand cupped below the eye.
- Open the eyes wide as if to stare.
- Continue to keep the eyes open and pull the lids sideways away from nose.
- Blink quickly and firmly.

Remove the second lens by following the same procedure.

Follow the required lens care procedures described under the heading: CARING FOR YOUR LENSES.

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

CARING FOR YOUR LENSES

Basic Instructions

For continued safe and comfortable wearing of your lenses, it is important that you clean and rinse, then disinfect your lenses after each removal using the care regimen recommended by your eye care practitioner. Cleaning and rinsing are necessary to remove mucus, secretions, films, or deposits, which may have accumulated during wearing. The ideal time to clean, rinse and disinfect your lenses is immediately after wearing them. Disinfecting is necessary to destroy harmful germs.

You should adhere to a recommended care regimen. Failure to follow the regimen may result in development of serious ocular complications as discussed in the WARNINGS section of the Package Insert.

When you first receive your lenses, practice how to put the lenses on and how to remove them while you are in your eye care practitioner's office. At that time you will be provided with a recommended cleaning and disinfection regimen and, instructions and warnings for lens care, handling, cleaning, and disinfection. Your eye care practitioner should instruct you about appropriate and adequate procedures and products for your use.

For safe contact lens wear you should know and always practice your lens care routine.

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use fresh unexpired lens care solutions.
- Use the recommended system of lens care which is 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 systems unless indicated on solution labeling.**
- Always remove, clean, rinse, enzyme and disinfect your lenses according to the schedule prescribed by your eye care practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.
- To avoid contamination, do not use saliva, tap water or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.

Your eye care practitioner will recommend his/her preferred, FDA approved lens care solutions for the cleaning, disinfection, storage and lubrication of your Paragon RG-4™ rigid gas permeable contact lenses.

Follow the instructions provided with each lens care solution. Failure to adhere to these procedures may result in the development of serious ocular complications. A patient should not switch from one care system to another unless it has been determined by the eye care practitioner that this is necessary. Do not mix or alternate the disinfection and storage systems unless so indicated on the product label.

Always wash and rinse your hands thoroughly before handling your contact lenses.

1. Clean

Clean one lens first (always start with the same lens first to avoid mix-ups). Place the lens, front side down, in the palm of the hand and apply several drops of cleaning solution. Using the index finger of the other hand, apply slight pressure in a swirling motion for the time recommended by the cleaning solution manufacturer. Do not clean the

lens by rubbing it between the thumb and index fingers, as this may cause lens warpage. Patients should follow the complete recommended lens rubbing and rinsing times in the product labeling to adequately disinfect the lenses and reduce the risk of contact lens contamination. Reduced rubbing or rinsing times may not adequately clean their lenses.

2. Rinse

Rinse the lens thoroughly as recommended by your lens care product manufacturer to remove the cleaning solution, mucus, and film from the lens surface. Place that lens into the correct chamber of the lens storage case. Then repeat the clean and rinse procedure for the second lens.

3. Disinfect

After cleaning and rinsing the lenses disinfect them by using the system recommended by your eye care practitioner and/or the lens manufacturer. Follow the instructions provided in the disinfection solution labeling.

4. Storage

To store lenses, disinfect and leave them in the closed case until ready to wear. If lenses are not to be used immediately following disinfection, you should consult the storage solution package insert or your eye care practitioner for information on storage of your lenses.

Always keep your lenses completely immersed in a recommended disinfecting/conditioning solution when the lenses are not being worn. If you discontinue wearing your lenses, but plan to begin wearing them again after a few weeks, ask your eye care practitioner for a recommendation on how to store your lenses.

Note: Paragon RG-4™ Contact Lenses for Corneal Reshaping cannot be heat (thermally) disinfected.

5. Care of Your Lens Case

Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, fill your lens case with fresh solution every time you store your lenses and never re-use solution. Discard the solution immediately after lenses have been removed from the lens case. Lenses should not be stored or rinsed with tap water, bottled water or any non-sterile solution. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.

6. Lubricating/Rewetting

Your eye care practitioner will recommend a lubricating/rewetting solution. Lubricating/Rewetting solutions can be used to rewet (lubricate) your lenses while you are wearing them to make them more comfortable.

Lens Deposits and Use Of Enzymatic Cleaning Procedure

Your 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 the well-being of your 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, you should carefully follow the instructions in the enzymatic cleaning labeling.

Care For A Sticking (Nonmoving) Lens

If the lens sticks (stops moving) or cannot be removed, you should apply 5 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 nonmovement of the lens continues after 30 minutes, you should IMMEDIATELY consult your eye care practitioner.

EMERGENCIES

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes, you should:

- FLUSH YOUR EYES IMMEDIATELY WITH TAP WATER.
- REMOVE YOUR LENSES.
- IMMEDIATELY CONTACT YOUR EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

WEARING SCHEDULE

Typically, your practitioner will start your overnight wear the first night. You should place the lens in your eye 15 to 20 minutes before going to sleep. A well fit lens provides for centration with the closed eye. The effects of lid interaction on blinking and gravity may result in lens decentration during open eye wear.

Be aware, “when in doubt, take it out”. It is important that the new wearer not sleep in a lens that has a significant foreign body sensation. In the event of foreign body sensation, remove the lens, clean and rewet it; and, again place the lens in your eye. If the sensation continues, remove the lens. The lens should not be worn.

Your practitioner will schedule a follow-up evaluation the morning after the first overnight wear. The visit is best scheduled within a few hours of awakening and you should report with your lenses in place. This visit provides an excellent opportunity to evaluate lens centration and potential lens adherence.

Assuming the absence of clinical signs and complications, you will be instructed to continue overnight wear of the lenses until the next scheduled follow-up visit.

The cornea normally changes within five to eight hours of wear. Your practitioner should modulated your wearing time to determine the MINIMUM wear required for myopic reduction. The average wearing time is between 8 and 10 hours. Attempt to maintain wearing time at this minimum level.

Myopic Reduction Maintenance Lens (Retainer Lens) Schedule

The Retainer Lens schedule must be customized for each patient. The Retainer Lens wearing time begins with the same wearing time required for the last fitted Paragon RG-4™ contact lenses for overnight Contact Lens Corneal reshaping. After a period of several days, or when the eye care practitioner is satisfied that the patient has adapted to the first Retainer Lenses, the patient may attempt to skip a night of wear to monitor the duration of visual improvement. This may continue for as long as the patient can see clearly. When it is found that the patient experiences a visual decrement following lens removal, the schedule of overnight wear must be modulated to maintain visual performance.

Note: To maintain the Contact Lens Corneal Reshaping effect of myopia reduction overnight lens wear must be continued on a prescribed schedule. Failure to do so can affect daily activities (e.g., night driving), visual fluctuations and changes in intended correction.

Manufacturer:

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