

Paragon Thin™ (paflucocon C)

Rigid Gas Permeable Contact Lenses for Daily Wear

Paragon HDS® (paflucocon B)

Rigid Gas Permeable Contact Lenses for Daily Wear and Extended Wear

Paragon HDS® 100 (paflucocon D)

Rigid Gas Permeable Contact Lenses for Daily Wear and Extended Wear

Instructions For Wearers



INSTRUCTIONS FOR WEARERS

Patient Name _____

Date Dispensed _____

Lens Dispensed

Material

- Paragon Thin™ Daily Wear* without UV
- Paragon Thin™ Daily Wear* with UV

- Paragon HDS® Daily Wear* without UV
- Paragon HDS® Daily Wear* with UV
- Paragon HDS® Extended Wear without UV
- Paragon HDS® Extended Wear with UV

Design

- Spherical
- Aspheric
- Bifocal
- Toric
- Other

- Paragon HDS®100 Daily Wear* without UV
- Paragon HDS®100 Extended Wear without UV

*** DO NOT sleep in these lenses.** Daily Wear contact lenses should be only worn on a daily schedule.

Lens Prescription

Eye	Base Curve	Power	Diameter	Color	Lot Number
Right					
Left					

Prescribed By

Dr. _____

Address _____

Phone _____

My cleaning and disinfecting system is:

Convention: Reference to HDS® rigid gas permeable contact lenses indicates all three materials - Paragon

HDS® (paflucocon B), Paragon Thin™ (paflucocon C) and Paragon HDS® 100 (paflucocon D).

Your HDS® rigid gas permeable contact lens may be tinted as a handing aid for locating the lens. These products may be plasma treated.

HDS® rigid gas permeable contact lenses are available with an ultraviolet absorber. The ultraviolet absorber, Acrymer™ (4-methacryloxy-2-hydroxybenzophenone), has been integrated as an additive within the HDS® polymer matrix blocking up to 96% of light below 380 nm.

CAUTIONS: Federal (US) law restricts this device to sale by, or on the order of a licensed eye care practitioner.
Nonsterile. Clean and condition prior to use.

NOTE: See the Package Insert for additional safety information.

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use of your contact lenses and lens care products, including the lens case.

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.

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 lens 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.

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; THEREFORE, IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, OR REDNESS OF THE EYE, OR OTHER PROBLEMS WITH YOUR EYES, IMMEDIATELY REMOVE YOUR LENSES, AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.

INSTRUCTIONS FOR WEARERS

Table of Contents

	<u>Page</u>
Introduction	1
Lens Discussion	1
Lens Handling	2
Lens Placement	2
Centering A Lens	2
Lens Removal	3
Lens Care	3
Precautions	5
When To Call Your Eye Care Practitioner	6
Personal Wearing Schedule Record	6
Warning	7
How Supplied	7

Introduction

Your eyes need oxygen to stay healthy and to keep you seeing well and feeling well. But, unlike all the other organs of your body, your eyes do not rely on the blood for oxygen. Instead they receive oxygen directly from the air and from the tears that continually bathe them. That's why it is important that today's contact lenses allow oxygen to pass through them so that the oxygen in the air can reach the eye's tissues. Just as importantly, contact lenses must be fitted properly by an eye care professional so that they will allow and, in fact, promote the movement of oxygen-rich tears around and underneath them.

Your eye care professional can prescribe HDS[®] rigid permeable contact lenses in variety of prescriptions and designs depending upon your vision correction needs. In addition, your eye care professional will determine what type of wearing schedule is best suited for you. If a daily wear schedule is prescribed, you must remove, clean, and disinfect your lenses every day and leave them out overnight while you sleep. If an extended wear schedule is recommended, you may wear your contact lenses overnight while you are sleeping for up to seven nights before they must be removed for cleaning and disinfection. Not everyone who can wear HDS[®] rigid gas permeable contact lenses on a daily basis will be able to wear them on an extended-wear schedule. In many cases, the eye care professional may prescribe a two-week period of daily wear during which your eyes can adapt to the new lenses, prior to initiating extended wear.

Not all HDS[®] rigid gas permeable contact lenses have been tested for safety in extended wear. The following table summarizes which lens designs are currently recommended for daily wear and extended wear. For safe, successful contact lens wear follow your eye care professional's recommended wearing schedule.

Lens Design and Type*	Paragon Thin [™] (paflucocon C)	Paragon HDS [®] (paflucocon B)	Paragon HDS [®] 100 (paflucocon D)
Spherical DW	yes	yes	yes
Spherical EW	NO	yes	yes
Aspherical DW	yes	yes	yes
Aspherical EW	NO	yes	yes
Toric DW	yes	yes	yes
Toric EW	NO	NO	NO
Bifocal DW	yes	yes	yes
Bifocal EW	NO	NO	NO
Other** DW	yes	yes	yes
Other** EW	NO	NO	NO

* DW = daily wear; EW = extended wear

** Other lenses are used to correct keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, LASIK or radial keratotomy surgery.

Lens Discussion

HDS[®] rigid gas permeable contact lenses are used for vision correction in people whose eyes are normal, healthy, and free of disease. Depending upon design, they may be used to correct myopia (nearsightedness), hyperopia (farsightedness), presbyopia (reduced ability to focus at near and intermediate ranges associated with aging), astigmatism (distorted vision due to an irregularity of one or more of the eye's light-bending surfaces), and irregular corneal conditions (e.g. keratoconus, pellucid marginal degeneration, following surgery). HDS[®] rigid gas permeable contact lenses should not be used to correct aphakia, a condition that results when the eye's lens is removed during cataract surgery.

Lens Handling

Before touching your HDS® rigid gas permeable contact lenses, wash your hands and rinse them thoroughly. Soaps, oils, perfumes, or nicotine transferred from your hands to the lenses will cause irritation, including itching, burning, or stinging. Continued irritation could cause increased tearflow, red eyes, swollen eyelids, and sensitivity to light. Also, irritation can cause your eyes to secrete oils which can coat your lenses and, in turn, interfere with your vision.

Handle the lenses gently. They are easily scratched or marred. To remove a lens from the storage container, simply pour it out into the palm of your hand. Never use tweezers or other tools. Avoid scraping lenses against the storage case as scratches will occur. To pick up a lens, put a drop of wetting solution on your fingertip. Touch the lens gently. It will adhere to your fingertip.

Do not wipe lenses with even the softest tissues as they will leave microscopic scratches that can distort vision and may even cause eye problems.

Lens Placement

To place your HDS® rigid gas permeable contact lenses on your eyes, follow these simple steps. Always start with the right contact lens to avoid switching your lenses. Work over a flat surface such as a table or counter top.

1. Wash, rinse, and dry your hands.
2. Pour the lens from the storage container into the palm of your hand.
3. Inspect the lens to assure that it is clean and wet. Use your thumb and forefinger to apply more wetting solution if it is needed.
4. Apply a few drops of wetting solution to the tip of the forefinger of your right hand and then place the clean, wet lens on that fingertip with the concave (back) surface up.
5. Tilt your head down and fix your eyes straight down on the working surface. Keep both eyes open.
6. Place the middle finger on the margin of the upper right eyelid. Pull the lid upward. Avoid touching the eyelashes with the lens.
7. Place the right middle finger on the margin of the lower lid and pull it down.
8. Bring the right forefinger with the lens toward the cornea (the clear window that covers the iris or colored part of the eye). Look straight at the lens.
9. Place the lens gently on the cornea. Release the lower lid first and then the upper lid. Release the lids slowly to avoid dislodging the lens.
10. Repeat these steps with the left lens and left eye.

Centering A Lens

Sometimes during placement, removal, or just routine lens wear, a lens may be displaced onto the sclera (the white portion) of your eye. Do not be alarmed. The lens is easily re-centered.

Start by looking directly into a mirror. Pull the eyelids apart as widely as possible. Once you've located the lens on the sclera, look in the opposite direction of where the lens is located and close your eyes. Place your forefinger and middle finger over the closed lids adjacent to the lens on the side opposite of the direction you will need to move the lens. Gently, but firmly, massage the eye while slowly turning your eyes toward your fingertips. Never use your fingernails to try to loosen a lens or re-center one.

Your eye care professional may suggest alternate methods for lens insertion, re-centering and removal.

Lens Removal

Removing a lens is easier if it is centered on the cornea. If the lens is off center, re-center it before proceeding with these steps.

1. Tilt your head down so that it is parallel with the work surface.
2. Place your left hand, palm up, below the eye from which you are removing the lens.
3. Keep your eyes wide open and look straight ahead at the palm of your left hand.
4. Place the right middle finger on the eyelids where they meet at the outer corner of the eye. Pull the outer corner up and out. At the same time look downward and blink. The lens should fall easily off the eye and into the palm of your hand.

Lens Care

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 removing 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.

1. Always wash, rinse, and dry hands before handling contact lenses.
2. Always use fresh unexpired lens care solutions.
3. 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.**
4. 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.
5. 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 HDS[®] 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 eye 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 system unless so indicated on the product label.

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 and rinsing times may not adequately clean the 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 the lens into the correct chamber of the lens storage case. Then repeat the 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 worn 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 Thin™, Paragon HDS® and Paragon HDS® 100 contact lenses cannot be heat (thermally) disinfected.

5. Care of Your Lens Case

Contact lens cases can be a source of bacteria 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.

Precautions

For safe, successful contact lens wear, always follow the instructions given to you by your eye care practitioner. Additional safety information is contained in this booklet and the HDS Package Insert.

Wash and rinse your hands thoroughly before handling the lenses. Cosmetics, lotions, soaps, and creams must not come in contact with the lenses since eye irritation may result. If hair spray is used while the lenses are being worn, keep your eyes closed until the spray has settled.

HDS[®] rigid gas permeable contact lenses should not be worn while in the presence of noxious and irritating vapor.

Before leaving your eye care practitioner's office, you should be able to remove your lenses promptly or have someone else be able to remove them for you.

Do not swim with your lenses in place.

The safety of HDS[®] rigid gas permeable contact lenses with medication or contact lens solutions other than those recommended has not been established.

If a lens is not moving on the eye, apply one to three drops of the recommended lubricating solution directly to the eye. If, after several minutes, the lens still cannot be removed, apply more lubricating solution every few minutes. If you are still unable to remove the lens, consult an eye care practitioner immediately.

Always inform your doctor and other health care practitioners that you wear contact lenses.

Always consult your eye care practitioner before using any medicine in your eyes.

Always inform your employer that you wear contact lenses as some jobs may require use of eye protection equipment or may require that you do not wear contact lenses.

As with any contact lens, follow-up visits are necessary to assure health. Check with your eye care practitioner for a schedule.

Wearing Schedule For Extended Wear

Not every person is able to wear Paragon HDS® (paflucocon B) and/or Paragon HDS® 100 (paflucocon D) rigid gas permeable contact lenses on an extended wear basis, nor is this advised. Consideration needs to be given to a number of clinical and life-style factors. Consult your eye care practitioner for determination of the extended wear schedule. An initial 14-day daily wear period is recommended prior to overnight wear. Regular checkups as determined by the eye care practitioner, are extremely important. Lenses should be removed at least once every week (7 days) for cleaning and disinfection.

Extended wear lenses should not be used to correct keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, LASIK or radial keratotomy surgery.

DAY	SUGGESTED HOURS	HOURS WORN
15 (and after)	24 hours	

WARNING

The risk of ulcerative keratitis has been shown to be greater among wearers of extended wear lenses than among wearers of daily wear lenses. The risk among extended wear lens wearers increases with the number of consecutive days that lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning of the lens storage case. Additionally, smoking increases the risk of ulcerative keratitis for contact lens wearers.

It is recommended that contact lens wearers see their eye care practitioners twice each year or, if directed, more frequently.

How Supplied

Each HDS® 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%). The case, packing slip or invoice is marked with the base curve, dioptric power, diameter, center thickness, inclusion of UV absorber, lot number, fill date and the color of the lens.

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

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 Fill Date. 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.

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