

PACKAGE INSERT

SportSight™ GP
(paflucocon C)

**INTENSELY TINTED RIGID GAS PERMEABLE CONTACT
LENSES FOR DAILY WEAR**

IMPORTANT

Please read carefully and keep this information for future use.

CAUTION: Federal Law Prohibits Dispensing Without a Prescription.

WARNING

**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. **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.**

SportSight™ GP (paflucocon C)

INTENSELY TINTED RIGID GAS PERMEABLE CONTACT LENSES FOR DAILY WEAR

Spherical, Aspheric, Toric or Bifocal
contact lenses for:

- Nearsightedness (myopia)
- Farsightedness (hyperopia)
- Astigmatism
- Presbyopia

Attenuation of bright light and glare reduction

DESCRIPTION

SportSight™ GP (paflucocon C) intensely tinted rigid gas permeable contact lenses for daily wear are available as lathe cut firm contact lenses with spherical, aspheric, bifocal or toric anterior, posterior or bitoric surfaces. The posterior curve is selected so as to properly fit an individual eye and the anterior curve selected to provide the necessary optical power to correct refractive error. A peripheral curve system on the posterior surface allows tear exchange between the lens and the cornea.

The SportSight GP (paflucocon C) intensely tinted rigid gas permeable contact lens material is a thermoset copolymer derived from fluoro-silicone acrylate monomer.

The SportSight GP (paflucocon C) intensely tinted rigid gas permeable lenses deliver substantial attenuation of bright light and resultant reduction of glare. SportSight GP lenses help protect against transmission of harmful UV radiation to the cornea and into the eye. All environmental UV radiation (including UVA and UVB) is reduced to less than 1% transmission. Blue light (below 500nm) is reduced to less than 23% in SportSight Gray and is reduced to 15% in the recommended design.

*See further details and cautions under **UV Absorber** below.

The lenses have the following characteristics and dimensions.

- Refractive Index 1.466 (Nd at 25°C)
- Luminous Transmittance
(driving allowed)**8% to 26%
- Luminous Transmittance
(driving prohibited)** <8%

- Wetting Angle (Receding Angle) 12.8
- Specific Gravity 1.14
- Hardness (Shore D) 84
- Water Content <1%
- Oxygen Permeability $.30 \times 10^{-11}$ Dk* at 35°C

*(cm^2/sec)(mL O₂/mL x mm Hg) Revised Method of Irving Fatt, Ph.D.

**harmonic mean transmission over 4mm

Lens Parameters

- Chord Diameter 7.0 to 14.5 mm
- Center Thickness
(driving allowed) 0.09 to 0.275 mm
- Center Thickness
(driving prohibited) >0.275 mm
- Base Curve 6.50 to 9.00 mm
- Powers -20.00 to +12.00 D
- Bifocal Add Powers +0.25 to + 4.00 D
- Concentric Bifocal
Add Diameter 2.0 to 4.0 mm
- Monocentric Bifocal
Add Diameter 4.0 to 9.0 mm
- Monocentric Bifocal
- Prism 1.0 to 2.5 D

The SportSight GP (paflucocon C) intensely tinted, rigid gas permeable contact lenses are available in SportSight Gray. The SportSight Gray tinted lens contains D&C Red No. 17, D & C Green No. 6, and Perox Yellow No. 9.

ACTION

The SportSight GP (paflucocon C) intensely tinted rigid gas permeable spherical, aspheric, toric and bifocal contact lenses are intended for daily wear only.

When placed on the human cornea, the SportSight GP rigid gas permeable contact lens acts as a refracting medium to focus light rays upon the retina.

The toric lens provides for the individual meridional power requirements of the astigmatic eye. In the bifocal lens, the distance or near power prescription is provided in a small area with the near or distance prescription surrounding it.

The SportSight GP intensely tinted rigid gas permeable lenses deliver substantial attenuation of bright light and resultant reduction of

glare. SportSight GP lenses help protect against transmission of harmful UV radiation to the cornea and into the eye. All environmental UV radiation (including UVA and UVB) is reduced to less than 1% transmission. Blue light (below 500nm) is always reduced to less than 23% in SportSight Gray and is reduced to 15% in the recommended design.

INDICATIONS (USES)

The SportSight GP (paflucocon C) rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner.

The SportSight GP (paflucocon C) rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes who are nearsighted (myopic), farsighted (hyperopic) and who may exhibit corneal astigmatism up to 4.00 D that does not interfere with visual acuity. SportSight GP (paflucocon C) toric contact lenses are indicated to correct astigmatism of up to 6.00 D. SportSight GP bifocal lenses are indicated for presbyopic persons (farsighted or nearsighted) including astigmatic corrections up to 4.00 D requiring add power of up to + 4.00 D.

SportSight GP (paflucocon C) contact lenses are indicated for the attenuation of bright light and the reduction of glare. SportSight GP (paflucocon C) contact lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

Unless specifically labeled to the contrary, SportSight GP intensely tinted contact lenses meet the requirements of the ANSI Z80.3-1996 (Standard for Nonprescription Sunglasses and Fashion Eyewear) for daylight driving and for traffic signal recognition.

CONTRAINDICATIONS (REASONS NOT TO USE)

The SportSight GP intensely tinted rigid gas permeable contact lenses are contraindicated for use in low light activities where diminished vision due to reduced light transmission might present a danger to the wearer or others. SportSight GP lenses are also contraindicated by the presence of any of the following conditions.

- Acute or subacute inflammations of the anterior segment of the eye
- Any disease which affects the cornea or conjunctiva
- Insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that may affect the eye or be exacerbated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa which may be induced or exaggerated by wearing contact lenses and/or by using contact lens solutions
- Any active corneal infection (bacterial, fungal or viral)

WEARING SCHEDULE

THE WEARING SCHEDULE SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER.

Patients tend to overwear the lenses initially. It is important to adhere to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner, are also extremely important.

The maximum suggested wearing time for SportSight GP rigid gas permeable contact lenses is presented here.

DAY	1	2	3	4	5	6	7	8	9	10 to 14	15 & after
SUGGESTED HOURS	3	4	5	6	7	8	9	10	11	12	All daylight hours
HOURS WORN											

DO NOT SLEEP WHILE WEARING YOUR SportSight GP (paflucocon C) RIGID GAS PERMEABLE CONTACT LENSES. Studies have not been performed to show that the SportSight™ GP (paflucocon C) rigid gas permeable contact lens is safe to wear during sleep.

U.V. ABSORBER

SportSight GP intensely tinted rigid gas permeable contact lenses are only available with an ultraviolet light absorber. The ultraviolet

PRECAUTIONS

Follow the instructions below for the safe use of SportsSight GP lenses.

- Do not wear your SportSight GP lenses in combination with sunglasses when operating automobiles or machinery or when operating automobiles with darkly tinted windows.
- Always keep a spare pair of your regular eyewear with you when wearing SportSight GP lenses in case you encounter circumstances when SportSight GP lenses do not provide adequate visibility.
- Before you leave your practitioner's office, be able to promptly remove your lens or have someone else be able to remove your lens for you.
- **DO NOT WEAR YOUR SportSight GP RIGID GAS PERMEABLE CONTACT LENSES WHILE SLEEPING.**
- Always wash your hands with an additive free soap, rinse thoroughly and dry on a lint free towel before you handle your lenses. Eye irritation may result if cosmetics, lotions, soaps, creams and deodorants come in contact with your lenses and if the lenses are contaminated by infectious or non-infectious debris.
- Always follow the recommended lens care system for your SportSight GP lenses. Use the recommended lens care solutions and carefully follow the recommended directions.
- Always use FRESH rinsing, disinfecting and storage solutions.
- Do not use saliva or anything other than the recommended solutions to wet your lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn.
- Avoid using aerosol products such as hair-spray while wearing your lenses. If hair sprays are used, keep your eyes closed until the spray has settled, otherwise, the lenses may be damaged.
- Avoid all harmful or irritating vapors and fumes while wearing your lenses.
- Do not swim with your lenses in place.
- Never use tweezers or other tools to remove your lens from the lens container. Do not touch the lens with your fingernails.
- Always inform your doctor (general health-care practitioner) 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. Some jobs may require the use of protective eye equipment or may require that you not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure continued health. **CHECK WITH YOUR EYE CARE PRACTITIONER.**
- To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and finger.
- Do not heat the conditioning solution and lenses.
- If your lens sticks (stops moving) on the eye, follow the recommended directions for "Care for a Sticking Lens". The lens must move freely on the eye for the continued health of the eye. If non-movement of the lens continues, immediately consult your eye care practitioner.
- **CAUTION:** Non-sterile. Clean and condition lenses prior to use.

ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO)

The following problems may occur.

- Eyes sting, burn or itch (irritation)
- Comfort is less than when lens was first placed on eye
- Feeling of something in the eye (foreign body, scratched area, abrasion)
- Excessive pain
- 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 adverse effects, **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 body on it, or the problem stops and the lens appears undamaged, thoroughly clean, rinse and disinfect the lens; then reinsert it.
- If the problem continues, IMMEDIATELY remove your contact lens and consult your eye care practitioner.

When any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization, iritis, persistent stromal edema or GPC (giant papillary conjunctivitis) may be present. Immediately remove your lenses and seek professional identification of the problem and prompt treatment to avoid serious eye damage, including corneal scarring, opacification, blindness or loss of eye.

FITTING

Conventional methods of fitting rigid contact lenses apply to the SportSight GP rigid gas permeable contact lens. **However, due to the relationship between lens thickness and light transmission, strict restrictions have been imposed on manufacturers to assure lenses meet claimed transmission performance and are labeled correctly. For a description of fitting techniques and thickness requirements, refer to the Fitting Guide for SportSight GP rigid gas permeable contact lenses. Copies of which are available from:**

**Paragon Vision Sciences
947 E. Impala Ave.
Mesa, Arizona 85204.**

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION.

LENS CARE DIRECTIONS

Always wash your hands with an additive-free soap, rinse thoroughly and dry on a lint-free towel before you handle your contact lenses.

Never use tweezers or other tools to remove your lens from the lens container. Pour the lens into your hand.

SportSight GP rigid gas permeable contact lenses must be both cleaned and disinfected each time you remove them. One procedure does not replace the other. Cleaning is necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs. Leave the SportSight GP rigid gas permeable contact lenses in a storage solution (such as Opti-Soak Conditioning Solution) for a minimum of 4 hours or as indicated on the product label.

To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and finger. Clean one lens first. (The recommended procedure is to always clean the same lens first to avoid mix-ups). Rinse the lens thoroughly to remove the cleaning solution. Place the lens into the correct storage chamber and fill the chamber with the recommended disinfection system as recommended by your eye care practitioner. Clean and rinse the other lens in the same manner and place it in its chamber. Tightly close the top of each chamber of the lens storage case. To disinfect your lenses, leave them in the solution for at least 4 hours, or as indicated on the product label.

Do not heat the conditioning solution and lenses. Leave the lenses in the unopened storage case until you are ready to put them on your eyes. After you remove your lens from the lens case, empty and rinse your lens storage case with fresh, hot running tap water and allow it to air dry. When you next use the case, refill it with fresh storage solution.

SportSight GP rigid gas permeable contact lenses should be disinfected using only a chemical (not heat) disinfection system. The following is a list of products available for use with SportSight GP rigid gas permeable contact lenses. This is not an exclusive list. You may use other lens care solutions as recommended by your eye care practitioner. Follow the instructions provided with each lens care solution.

SYSTEM PROCESS	CHEMICAL (not heat) DISINFECTION SYSTEM
Cleaning	Opti-Soak Daily Cleaner, Opti-Clean II, Barnes-Hind GP Daily Cleaner, LC-65
Enzymatic Cleaners & Protein Removers	Opti-Zyme Enzymatic Cleaner, ProFree/GP Weekly Enzymatic Cleaner, Opti-Free Supracleans Daily Protein Remover
Disinfection & Soaking	Opti-Soak Conditioning Solution, Barnes-Hind Wetting and Soaking Solution, Wet-N-Soak Plus
Lubrication	Opti-Tears, Wet-N-Soak Rewetting Drops

PRODUCT LIST

Opti-Soak, Opti-Clean, Opti-Tears, Opti-Free Supracleans Daily Protein Remover and Opti-Zyme by Alcon Laboratories, Inc.

LC-65, Wet-N-Soak, ProFree/GP, Barnes-Hind Wetting & Soaking Solution, by Allergan Pharmaceuticals, Inc.

The directions in the package inserts for these products should be followed. 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.

CARE FOR A STICKING LENS

If the lens sticks (stops moving) on the eye, apply a few drops of a lubricating solution. Wait until the lens begins to move freely on your eye before removing it. If non-movement of the lens continues, immediately consult your eye care practitioner.

HOW SUPPLIED

Each lens is supplied non-sterile in an individual plastic case. The case, packing slip or invoice is marked with the base curve, dioptric power, diameter, center thickness, lot number, and driving restrictions of the lens.

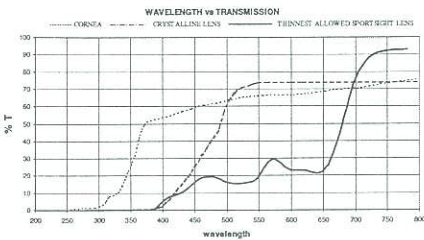
Paragon Vision Sciences

**947 E. Impala Ave.
Mesa, Arizona 85204**

Telephone: 1-800-528-8279
1-480-892-7602
1-480-926-7369 FAX

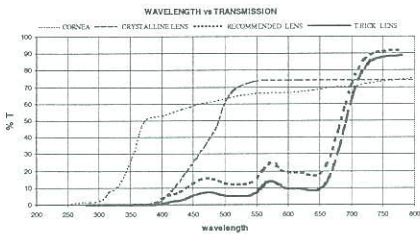
absorber, Uvinul D-49, has been integrated as an additive within the paflucocon C polymer matrix and, along with other components, blocks a minimum 99% of UVA, UVB, and other environmental UV. Uvinul D-49 is 2,2'-dihydroxy-4,4'-dimethoxybenzophenone.

NOTE: Long term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities) UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye care practitioner for more information.



**CORNEA- Human cornea from Lerman, S., Radiant Energy and the EYE, MacMillan, New York, 1980, p58, fig. 2-21.

***Crystalline Lens as described in Waxler, M., Hitchins, V.M., Optical Radiation and Human Health, CRC Press, Boca Raton, FL, 1986, figure 5.



The first of the above transmission charts shows the absorbance spectra of the natural ocular tissues compared to the thinnest available SportSight GP lens. The second chart shows the transmission spectrum that is obtained for lenses cut to recommended center thickness specifications for all powers from -20.0 diopters to + 2.5 diopters. The

second line represents the transmission spectrum of the thickest SportSight lens available which meets the traffic signal recognition requirements ANSI Z80.3-1996 (Standard for Nonprescription Sunglasses and Fashion Eyewear).

WARNINGS

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 practitioners directions and all labeling instructions for proper use of your contact lenses and lens care products. **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.**

UV-absorbing contact lenses are not substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. Persons should continue to use UV-absorbing eyewear as directed.

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

RESTRICTIONS

- SportSight GP Lenses only protect those ocular tissues behind the lens. Additional protection should be worn to protect the surrounding tissues under conditions of high and prolonged UV exposure such as snow fields and beaches.
- As with any sunwear, SportSight GP lenses reduce visible light transmission. Lens wear will not be suitable for some dark environments. Wearer should always reconsider their visual competence upon entering an indoor environment and remove their lenses if necessary.
- Do not operate a vehicle after dusk while wearing your lenses.