



INSTRUCTIONS FOR USE (Canada) THIS LEAFLET CONTAINS IMPORTANT PRODUCT USE AND SAFETY INFORMATION. PLEASE READ CAREFULLY AND RETAIN FOR FUTURE REFERENCE. CONTACT LENSES SHOULD ALWAYS BE FITTED BY AN EYE CARE PROFESSIONAL. IT IS ESSENTIAL THAT YOU FOLLOW YOUR EYE CARE PROFESSIONAL'S DIRECTIONS AND ALL LABELLING INSTRUCTIONS FOR PROPER USE OF YOUR CONTACT LENSES.



PRODUCT IDENTIFICATION (Name)

- PRECISION1™ (verofilcon A) One-Day Contact Lenses With UV Blocking Technology

PRODUCT DESCRIPTION

The lens material consists of approximately 51% water and 49% verofilcon A, a silicone containing hydrogel. The colour additive Reactive Blue 247 is added to the lens material to create a light blue edge-to-edge colour (handling tint) to make it easier to see when handling.

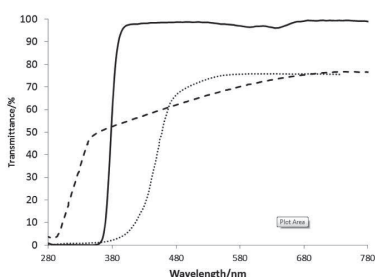
TECHNICAL PERFORMANCE CHARACTERISTICS

Lens Properties

- Refractive Index (hydrated): 1.4
Light Transmittance: > 90% (@ 640 nm, -3.00 D)
Oxygen Permeability (Dk): 90 x 10^-11 (cm^2/sec) (ml O2 / ml x mm Hg), measured at 35°C (intrinsic Dk-Coulometric method)
Water Content: 51% by weight in normal saline

Transmittance Curves

PRECISION1™ (verofilcon A) Contact Lens versus a Human Cornea and a Human Crystalline Lens



— Verofilcon A contact lens measured through central 6 mm portion for the thinnest marketed lens (-3.00 D, 0.090 mm center thickness)

- - - Human Cornea from a 24 year old person as described in Lerman, S., Radiant Energy and the Eye, MacMillian, New York, 1980, p.58, Figure 2-21.

..... Human crystalline lens from a 25 year old person as described in Waxler M. Hitchens V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, Figure 5.

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

Available Lens Parameters

- Chord Diameter: 14.2 mm
Center Thickness: 0.09 mm @ -3.00 D (varies with power)
Base Curve and Powers:
Spherical Lenses:
Base Curve: 8.3 mm
Minus Powers: -0.50 D to -6.00 D (0.25 D steps)
Plus Powers: +0.50 D to +6.00 D (0.25 D steps)

ACTIONS (Mode of Action)

When hydrated and placed on the cornea, verofilcon A soft contact lenses act as a refracting medium to focus light rays on the retina.

The lenses contain a UV blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye. The thinnest PRECISION1™ lenses (-3.00 diopters) block 93% UVA radiation and 99% UVB radiation.

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).

INTENDED PURPOSE / USE
Precision1™ Verofilcon A soft contact lenses are intended for on-eye use in persons with healthy eyes who need vision correction as determined and fitted by an eye care professional.

Intended Use Specific to Lens Design (Model)

Table with 2 columns: Lens Design (Model) and Intended Use (On-eye). Row: Spherical, Optical correction of refractive ametropia (myopia and hyperopia)

PATIENT TARGET GROUPS

The intended wearer population for verofilcon A soft contact lenses (spherical) includes those persons with non-diseased eyes who require vision correction (myopia and hyperopia), can be properly fitted with the device and are capable of understanding and following the wear, care, and safety instructions for use (or have a caregiver who can act on their behalf).

CLINICAL BENEFITS

Verofilcon A spherical soft contact lenses provide on-eye optical correction for myopia and hyperopia as determined and fitted by an eye care professional. Contact lenses with corrective power provide functional advantages over spectacles by improving peripheral (side) vision and by minimizing image size differences that result when the lens powers between the eyes are not the same.

INDICATIONS (Uses)

PRECISION1™ (verofilcon A) spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

PRECISION1™ (verofilcon A) soft contact lenses are to be used for single use, daily disposable wear (less than 24 hours while awake) only.

CONTRAINDICATIONS (Reasons Not to Use)

- Contact lenses should not be worn in conjunction with certain health or environmental conditions. Conditions that may prevent or interfere with safe contact lens wear include:
Allergy, inflammation, infection or irritation in or around the eye or eyelids
Inadequate tear film (dry eye)
Corneal hypoesthesia (reduced corneal sensitivity)
Use of any medication that is contraindicated or interferes with contact lens wear, including eye medications
Any systemic disease which may be exacerbated by or interferes with contact lens wear
If eyes become red or irritated

Consult your eye care professional specifically regarding these or other conditions.

WARNINGS

- Daily wear lenses are not indicated for overnight wear. Verofilcon A lenses should not be worn while sleeping.
Serious eye problems, including corneal ulcers (ulcerative keratitis), can develop rapidly and lead to loss of vision.
Contact lens wear increases the risk of eye infections. Sleeping in lenses and/or smoking further increases the risk of ulcerative keratitis for contact lens users (Cutter, 1996; Schein, 1989).

PRECAUTIONS

Special Precautions for the Eye Care Professional
When selecting an appropriate lens design and parameters, the eye care professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, central and peripheral thickness and optic zone diameter.

Lens Handling and Wearing Precautions
Check eyes daily to ensure they look well, feel comfortable and your vision is clear.

- If lens wear is discontinued for a length of time, consult your eye care professional before restarting wear.
Be careful while using soaps, lotions, creams, cosmetics or deodorants as they can cause irritation if they come into contact with your lenses.
Insert lenses before applying make-up and remove them before taking make-up off.
Always carry spare lenses with you or have back-up spectacles available.
Do not use lenses after the expiry date.

ADVERSE EFFECTS (Possible problems and what to do)

Problems may occur with contact lenses wear and may first present as one or more of the following signs and symptoms:

- Feeling of something in the eye (foreign body sensation)
Uncomfortable lens
Eye redness
Sensitivity to light (photophobia)
Burning, stinging, itching or watering eyes
Reduced sharpness of vision
Rainbows or halos around lights
Increased eye secretions
Discomfort or pain
Severe or persistent dry eyes
These symptoms, if ignored, may lead to more serious complications.

WHAT TO DO IF A PROBLEM OCCURS

If any of the above signs or symptoms occur, immediately remove the lens(es):

- Inspect the affected eye(s) in a mirror looking for signs of irregularity.
If the discomfort or problem stops, insert a fresh, new lens.
If the discomfort or problem does not stop or if it returns after insertion of a new lens(es), remove the lens(es) and immediately contact your eye care professional.

A serious condition such as infection, corneal ulcer (ulcerative keratitis), or iritis may be present. These conditions could progress rapidly and may lead to permanent loss of vision. Less serious reactions such as abrasions, epithelial staining and bacterial conjunctivitis must be managed and treated properly to avoid complications.

- Occasional dryness may be relieved by blinking fully several times or by the use of contact lens rewetting drops that are approved for use with soft contact lenses. If dryness persists, consult your eye care professional.

- If a lens sticks (stops moving), apply several drops of a contact lens rewetting solution and wait until the lens begins to move freely on the eye. If this problem persists, consult your eye care professional.

- If a lens decenters on the eye, it may be possible to recenter it by:
Closing your eyelids and gently massaging the lens into place, or
Looking in the direction of the lens and blinking gently, or
Gently pushing the off-centered lens onto the cornea with light finger pressure on the edge of the upper or lower eyelid.

- If a lens tears in your eye, remove the pieces carefully by pinching them as you would for normal lens removal. If the lens pieces do not seem to remove easily, do not pinch the eye tissue. Rinse with sterile saline and try to remove the lens pieces again. If this does not help, contact your eye care professional for assistance.

General Emergencies:
If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes:

- Flush eyes immediately with saline solution or tap water.
Remove and discard the lenses and immediately contact your eye care professional or visit a hospital emergency room without delay.

SERIOUS INCIDENT REPORTING

Any serious incident related to the use of this medical device should be reported to Alcon

Alcon Canada Inc.
2665 Meadowpine Blvd.
Mississauga, ON L5N 8C7
1-800-613-2245

DIRECTIONS FOR USE

Start each day with a fresh pair of lenses that are discarded at the end of every daily wearing period.

LENS HANDLING INSTRUCTIONS

- Always wash and rinse your hands thoroughly and dry with a clean, lint free towel before handling contact lenses.
Shake the blister pack gently prior to opening.
Remove the lens from the blister pack by carefully pouring it onto the palm of your hand.
Ensure the lens is right side out and that you have the correct lens for each eye.
Inspect the lenses prior to insertion.
Do not insert damaged or unclean lenses.

LENS INSERTION INSTRUCTIONS

- Wash and rinse your hands thoroughly, and dry completely with a clean, lint free towel before handling contact lenses.
Place a lens on the tip of your clean and dry right or left index finger. Place the middle finger of the same hand close to lower eyelashes and pull down the lower eyelid.
Use the fingers of the other hand to lift the upper eyelid.
Place the lens directly on the eye (cornea) and gently roll finger away from the lens.
Look down and slowly release the lower lid.
Look straight ahead and slowly release the upper lid.
Blink gently.

LENS REMOVAL INSTRUCTIONS

- Wash and rinse your hands thoroughly, and dry completely with a clean, lint free towel.
Blink fully several times.
While looking up, use the tip of your finger to slide the lens down onto the white part of the eye.
Remove the lens by pinching gently between the thumb and forefinger. Do not pinch the eye tissue.
If the lens is difficult to remove, dry your fingers once more and try again. Do not use rewetting drops in this instance.
Never use tweezers, suction cups, sharp objects or your fingernails to remove lenses from the lens container or your eyes.

If you experience problems with lens removal (lens decentered or damaged), see WHAT TO DO IF A PROBLEM OCCURS above.

LENS CARE SOLUTIONS

Verofilcon A daily disposable contact lenses are not intended for use with a lens care system. The lenses are for single use, daily disposable wear only. They are not intended to be cleaned or disinfected and should be discarded after a single use. Keep replacement lenses or back-up spectacles available at all times.

If lens drops are recommended by the eye care professional Alcon recommends the following products:

- Systane® ULTRA Hydration Lubricant Eye Drops
Systane® ULTRA Hydration Lubricant Eye Drops Preservative Free

DISPOSAL AND RECYCLING

Dispose of contact lenses and the blister pack lidding in the waste bin, not down the sink or toilet. The carton packaging and the polypropylene (PP) plastic shell of the blister pack should be placed in the waste bin or recycled according to local waste management guidance.

CONTENTS OF CONTAINER (How Supplied)

Each lens is packaged in a foil-sealed plastic blister pack containing phosphate buffered saline solution with approximately 0.3% of polymeric wetting agents consisting of copolymers of polyamidoamine and poly(acrylamide-acrylic) acid, and is steam sterilized. The package is marked with the base curve, diameter, dioptric power, manufacturing lot number, date of manufacture (when available), and expiration date.

Lenses are supplied sterile in cartons containing up to 90 individually sealed contact lenses.

REFERENCES

- Cutter GR, Chalmers RL, Roseman M. The Clinical Presentation, Prevalence, and Risk Factors of Focal Corneal Infiltrates in Soft Contact Lens Wearers. The CLAO Journal. Jan 1996; 22 (1): 30-37.
Schein OD, Glynn RJ, Poggio EC, Seddon JM, Kenyon KR. The Relative Risk of Ulcerative Keratitis Among Users of Daily-Wear and Extended-Wear Soft Contact Lenses. N Eng J Med. 1989;321(12):773-83.

ABBREVIATIONS AND SYMBOLS THAT MAY BE USED IN LABELLING

Table with 2 columns: ABBREVIATION / SYMBOL and DEFINITION. Includes entries for BC (Base Curve), DIA (Diameter), PWR (Power), D (Diopter/Lens power), L (Left), R (Right), UV (Ultra-violet), UVA (Ultra-violet A), UVB (Ultra-violet B), waste license sign, Do not re-use, LOT (Batch code), Use-by date, EXP (Expiration date), Single sterile barrier system, Sterilized using steam, CE (European conformity mark), Two letter code for the language, Caution, Consult instructions for use, Do not use if blister package is damaged, Manufacturer, Date of manufacture, Medical device, Authorized Representative in the European Community, Rx only (Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed eye care professional)

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099, USA

Depending on the date of production, the name and address of the Authorized Representative in the European Community assigned to these contact lenses are either:
Alcon Laboratories Belgium BVBA
Rijksweg 14, 2870 Puurs
Belgium
or
Alcon Laboratories Belgium
Lichterveld 3
2870 Puurs-Sint-Amands
Belgium

The assigned CE mark to a given product lot is identified on the product blister pack and carton label.

Depending on the date of production, the CE mark may be either:
CE 0086 or CE 0123

The assigned CE mark to a given product lot is identified on the product blister pack and carton label.

Alcon

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