

PROGENT

IMPORTANT : PLEASE READ CAREFULLY AND KEEP THIS PACKAGE INSERT FOR FUTURE USE.

Do not use this product unless you have received instructions from your eye care professional and clearly understand the Directions for Use.

Federal (or United States) law restricts this device to sale by or on the order of a licensed eye care practitioner.

For use with rigid gas permeable (fluoro silicone acrylate) contact lenses. **DO NOT USE WITH SOFT CONTACT LENSES INCLUDING HYDROGEL, SILICONE HYDROGEL OR HYBRID SOFT CONTACT LENSES.**

DESCRIPTION

Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses ("PROGENT") is the mixture of two sterile solutions, PROGENT A (sodium hypochlorite, sodium carbonate, sodium hydroxide, purified water) and PROGENT B (potassium bromide, sodium carbonate, purified water). PROGENT A and B are mixed in a PROGENT Vial. Allow lenses to soak in the PROGENT solution mixture for 30 minutes. Soaking for longer than 30 minutes is not recommended. PROGENT Rinsing Solution (sterile purified water) is provided for rinsing the lenses and Progent Vial. The PROGENT treatment is recommended every two weeks. The frequency may vary according to the condition of your lens. Follow your eye care professional's directions (to a maximum of every 5 days).

WARNINGS

DO NOT PUT PROGENT SOLUTION (A, B, OR MIXTURE) IN THE EYE.

Severe irritation, burning and stinging may result. If solution is accidentally put into the eye, immediately remove contact lenses if being worn and rinse the eye thoroughly for about 1 minute with sterile saline solution or sterile purified water or another appropriate rinsing solution. Seek medical attention.

DO NOT PUT PROGENT SOLUTION (A, B, OR MIXTURE) IN THE NOSE.

Severe irritation, burning and stinging may result. If solution is accidentally put into the nose, immediately rinse thoroughly for about 1 minute with sterile saline solution or sterile purified water or another appropriate rinsing solution. Seek medical attention.

DO NOT TAKE PROGENT SOLUTION (A, B, OR MIXTURE) INTERNALLY.

If solution is accidentally swallowed, drink a large quantity of water. Seek immediate professional medical assistance or contact a poison control center.

DO NOT ALLOW SKIN CONTACT.

If solution is spilled on the skin, wash thoroughly with running tap water for about 1 minute.

After cleaning with PROGENT, **lenses should be cleaned with a daily cleaner and disinfected** as recommended by your eye care professional. Failure to do so may result in eye irritation, burning, or stinging. Serious injury to the eye and loss of vision may result from problems with contact lenses and lens care solutions. Eye problems, including corneal ulcers and infections, can develop rapidly. Immediately remove your lenses and call or visit your eye care professional if you experience any adverse reactions such as: eye discomfort, excessive tearing, vision changes, pain, unusual eye discharge, sensitivity to light, or redness of the eye.



ACTIONS

PROGENT loosens and removes deposits, such as protein deposits, that may cause irritation and/or discomfort from contact lenses.

INDICATIONS (USES)

PROGENT, when used as directed, cleans and removes protein deposits from fluoro silicone acrylate RGP contact lenses.

CONTRAINDICATIONS (REASONS NOT TO USE)

Do not use PROGENT if you are allergic to any ingredient in the product. **DO NOT use with soft contact lenses including hydrogel, silicone hydrogel or hybrid soft contact lenses.**

PRECAUTIONS

- Always wash and rinse your hands before handling contact lenses.
- Use only freshly mixed PROGENT solution and discard immediately after use. Never reuse the solution.
- PROGENT (both Progent A and Progent B) and PROGENT Rinsing Solution containers are for single use only and should be discarded after use.
- Soaking for longer than 30 minutes is not recommended because it may cause lens discoloration.
- DO NOT spill PROGENT solution on clothes. It may bleach them. Wash clothes immediately.
- Use only PROGENT Vial. Do not use any other container for solution mixing and lens cleaning with PROGENT.
- Use before the expiration date marked on the single-use containers and outer carton.
- Keep out of reach of children.
- Store at room temperature.

ADVERSE REACTIONS (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 the eye, feeling of something in the eye (foreign body, scratched area), excessive watering (tearing) of the eye, unusual eye secretions, redness of the eye, reduced sharpness of vision (poor visual acuity), blurred vision, rainbows or halos around objects, sensitivity to light (photophobia), or dry eyes.

If you notice any of the above, **IMMEDIATELY REMOVE YOUR LENSES.**

- If the **lens is in any way damaged**, DO NOT REINSERT.
- If the lens does not appear to be damaged and there is not discomfort or a problem, thoroughly clean, rinse and disinfect the lens, then reinsert it. If any discomfort or problem occurs, IMMEDIATELY remove the lens and consult your eye care professional for identification of the problem and, if necessary, obtain treatment to avoid serious eye damage.
- If PROGENT solution is **accidentally put into the eye or nose**, wash thoroughly for about 1 minute with sterile saline solution or sterile purified water or another appropriate rinsing solution. Consult your eye care professional or other healthcare practitioner and, if necessary, obtain treatment to avoid serious damage.
- If PROGENT solution is **accidentally swallowed**, drink a large quantity of water. Seek immediate professional medical assistance or contact a poison control center.
- If PROGENT solution is **accidentally spilled on the skin**, wash thoroughly with running tap water for about 1 minute.

All adverse reactions observed while using PROGENT should be reported to:

Menicon America Inc.
Waltham, MA 02451
1-800-MENICON (1-800-636-4266)

DIRECTIONS FOR USE

WARNINGS: Do not allow Progent solutions to touch skin, eyes or clothing. Use ONLY enclosed PROGENT Rinsing Solution for rinsing lenses & PROGENT Vial. To help prevent infections, DO NOT rinse with tap water.

Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If your lenses have been submersed in water such as when swimming in pools, lakes or oceans, you should thoroughly clean and disinfect them before insertion.

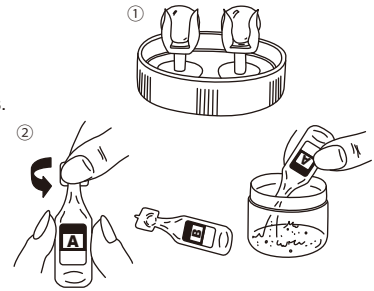
Ask your eye care professional for recommendations about wearing your lenses during any activity involving water.

Please read and follow the instructions carefully in the following order.

Wash and rinse hands before handling contact lenses.

① Place lenses in Left (L) or right (R) holder in top of PROGENT Vial before mixing solutions.

- ② Open PROGENT A container by gently twisting above the neck. Hold upright and do not spill on hands or clothes when opening. Fill PROGENT Vial with Progent A (completely empty container into PROGENT Vial). Discard PROGENT A container immediately. Open PROGENT B, empty completely into PROGENT Vial and discard container. Keep discarded containers out of reach of young children.



NOTE: Mixed A & B solution should be used immediately.

- ③ Tightly close the cap of the PROGENT Vial and shake gently several times.



- ④ Allow lenses to soak in PROGENT mixture for 30 minutes (soaking longer than 30 minutes is NOT recommended).

DO NOT remove lenses from holders before rinsing. Your fingers SHOULD NOT touch the Progent solution.



- ⑤ Remove PROGENT Vial cap and keep lenses in PROGENT Vial holders (**do not spill solution**). Discard PROGENT mixture into sink with running tap water.
- ⑥ Open PROGENT Rinsing Solution container by twisting gently above the neck. Empty entire contents into PROGENT Vial. Replace PROGENT Vial cap tightly (with lenses still in holders) and gently shake the vial.
- ⑦ Open the vial and remove lenses from holders. Clean and disinfect lenses using the solutions and procedures recommended by your eye care professional. Follow the labeling instructions on the solution(s) package(s) or package insert(s).
- ⑧ After lenses have been removed from PROGENT Vial holders, discard PROGENT Rinsing Solution into sink with running tap water. Allow PROGENT Vial to air dry.

Wash hands after completing all steps.

Treat lenses with PROGENT every two weeks (to a maximum of every 5 days) according to your eye care professional's directions. Frequency may vary according to the condition of your lenses. Replace PROGENT Vial with every purchase of PROGENT.

HOW SUPPLIED

PROGENT is supplied in 7-treatment or 1-treatment packages. The 7-treatment package consists of seven 5 mL containers of PROGENT A solution, seven 5 mL containers of PROGENT B solution, seven 10 mL containers of PROGENT Rinsing Solution and 1 PROGENT Vial. The 1-treatment package consists of one 5 mL container of PROGENT A solution, one 5 mL container of PROGENT B solution, one 10 mL container of PROGENT Rinsing Solution and 1 PROGENT Vial. PROGENT A, PROGENT B and PROGENT Rinsing Solution containers are for single use ONLY. The outer carton and each solution container are marked with a lot number and expiration date.

Distributed by :
Menicon America Inc.
Waltham, MA 02451
1-800-MENICON (1-800-636-4266)

STERILE

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