Contact Lenses; Instruction for Use:

- It is essential that patients be instructed to remove any and all solutions on the lens case.
- If air drying, be sure that no residual solution remains in the case lids after use without any additional cleaning methods.
- Never use water. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with fresh, clean tissues.
- Sterile unpreserved solutions, when used, should be applied directly to the lens case.

PRECAUTIONS

- Special Precautions for Eye Injuries:
  - Doses (contact lens solutions) and contact lenses manufactured from the Synergis® material are safe and effective for daily wear.
  - Due to the small number of patients enrolled in clinical investigation of lenses, all reprocessing, design changes, and manufacturing changes are followed by appropriate studies to assure continued safety.
  - Consequently, when selecting an appropriate lens design and parameters, the prescriber should consider all characteristics of the lens except for safety and the need for continuing ocular health of the patient and patient performance on the eye should be carefully monitored by the prescribing ophthalmic and contact lens care professionals.

- Prescription Warning:
  - The lens should have a +1.00 D power with at least 60% water content. Repeated wearing of the lens should be stopped immediately if any discomfort is present.

- Use only the suggested commercial lens care system which can be seen in the center of the Duette® Hybrid Contact Lens Instruction for Use label.

- This patient is recommended. Never air dry or recap the lens case.

- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, instruct patients to throw away the lens and no longer use it.

- Contact lenses and lens care products, including the lens case.

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Subjects with nearsightedness to the elderly be cleaned, rinsed, and disinfected each time they are removed. Cleaning and disinfecting the two cohorts. Lens replacements were greater in the Test cohort (75%) and dexamethasone HCl 0.1% (0.3%) in test cohort and 0.1% in control cohort (75%). Three (3) of the 5 adverse events were reported for the test cohort and 1 adverse event reported for the control cohort (2 out of 1 control) were reported as serious adverse events. Results of the slit lamp examination showed the test cohort eyes presenting with more normal vision compared to the control cohort examinations. All other slit lamp findings were reported a similar ratio and severity when looking at the combined visit findings for both the test and control cohorts. Symptoms and complaints were compared between the test and control cohorts against the baseline presentation.

General Lens Care (Clean and rinse then disinfect lenses)

- Carefully follow the instructions in the enzymatic cleaning guidelines on the lens care regimen recommended for the patient:
  - Rinse and wipe the lens to remove protein deposits from the surface of the lens. Store the lens in a clean, dry container. Do not soak the lens in hydrogen peroxide.
  - After reapplication of the lens, if the problem continues, the patient should IMMEDIATELY remove the contact lens and contact the eyecare practitioner.

Wearing and lens replacement schedules should be determined by the eyecare practitioner. The lens care products listed below are recommended by Synergeyes for use with the Synergeyes Dual Hybrid Contact Lenses. For use with the lenses listed below, the patient should be instructed to:

- Use the product as directed by the eyecare practitioner. The product is supplied in a sterile glass vial. The lens is shipped wet in 0.9% buffered sodium chloride solution.

REPORTING OF ADVERSE REACTIONS

All Serious Adverse Events and adhesion reactions observed in patients wearing Dual Hybrid Contact Lenses or experienced with the lenses should be immediately reported to:

Synergeyes, Inc., Carlsbad, CA 92008 www.synergeyes.com Tel: (760) 476-9480 FAX: (760) 476-9484

Authorized Representative (European Union): EuroEyes: Molenstrat 15; The Hague; 2513 BT; The Netherlands; Tel: +31 70 345 8777

HOW SUPPLIED

The Dual Hybrid Contact Lenses is supplied in a sterile glass vial. The lens is shipped wet in 0.9% buffered sodium chloride solution. The vial is labeled with the control equivalent base curve radius, slit curve radius, droplet power, overall diameter, lot number, and expiration date. In addition, the vial should show icons for Rx Only and Sterile marks. The package carton is engraved with the control equivalent base curve radius, slit curve radius, droplet power, overall diameter, and lot number.

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