The lenses may be prescribed for daily wear with removal for cleaning and disinfection (chemical, heat, or ultraviolet) prior to reinsertion, as recommended by the eyecare practitioner.

CLAIMS OF REASONS NOT TO USE
DO NOT USE Duette Hybrid Contact Lenses when any of the following conditions exist:

- Acute and subacute conjunctivitis or any inflammation of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- Severe insufficiency of tears (dry eyes) if they become red or irritated.
- Corneal hypoesthesia.
- Any systemic disease that may affect the eye or be exacerbated by wearing contact lenses.
- Allergic reactions of eye surfaces or allergic to agents that may be used to disinfect contact lens solutions.
- Use of a contact lens with a mercury or Thimerosal, in a solution which is to be used to care for Duette® Brand Hybrid Contact Lenses (Hybrid Contact Lens with a silicone hydrogel skirt).
- Use of oral medications or systemic medication that may interfere with contact lenses.
- Neovascularization or pterygium of the conjunctiva from the limbus.
- Any active corneal infection (bacterial, fungal, or viral)

WARRNINGS: PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN ...

It is essential that patients follow the directions of the eyecare practitioner and all labeling instructions for proper use of contact lenses and lens care products, including the lens case. Patients should be advised of the following instructions for use and warnngs pertaining to contact lens care.

Storing and Storing Lenses: Instruction for Use:

Patients should be instructed to use only fresh multi-purpose (contact lens disinfecting) solution every time they use contact lenses. Wearing lenses for longer periods of time without disembracing them is not recommended. A fresh multi-purpose solution must be used each day. Patients must be instructed to never use water, saline solution, or rewetting drops to disinfect their lenses. These solutions will not disinfect their lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.

b. Low and Rimmed Tone

Instruction Booklet for Duette Hybrid Contact Lenses. As the lenses have been manufactured from the SynergEye materials are safe and effective for daily wear. Due to the small number of patients enrolled in clinical investigation of lenses, minimal adverse, non-surgical effects, crosslinking and UV blockers.

DESCRIPTION

Duette® Hybrid Contact Lenses are made of highly permeable rigid gas permeable material (polymer) and a poly-silicone hydrogel material (hematogen-α). The lenses are designed to have at least four zones on the anterior and posterior surfaces:

- RGP Material: Thinner, more opaque, front and or back zone, ocular surface.
- Silicone: The intermediate curvature zone.
- Hydrogel: The peripheral anterior edge taper and posterior hydrogel.
- Material: A oligomeric terminus smoothly joining the anterior taper to the peripheral edge terminus.

Duette® Hybrid Contact Lenses for hyperopia and myopia with or without astigmatism, and presbyopia are for daily wear. The center of the lens is a thermoset fluorosilicone acrylic copolymer derived primarily from trimethyl silicate, aliphatic siloxane methylcarlate; hydroxyethoxymethyl methacrylate, hydrophilic methacrylate, cross linkers and UV blockers.

For presbyopia, add powers for Duette Multiscleral and Duette Progressive Contact Lens near lenses are between +0.15 D and +0.18 D. For presbyopia, add powers for Duette Progressive Contact Distance lenses are between +0.30 D and +0.18 D.
SUMMARY OF CLINICAL STUDY

A three month clinical study of the Duette® Contact Len...