FOCUS® DAILIES®, FOCUS® DAILIES® Toric, FOCUS® DAILIES® Progressives, DAILIES® AquaComfort Plus®, DAILIES® AquaComfort Plus® Toric and DAILIES® AquaComfort Plus® Multifocal (nelfilcon A) One-Day Contact Lenses

NOTATIONS

5. Special Precautions for the Eye Care Professional Due to the small variation of tolerances involved in the clinical investigation of lenses, all refractive power, design configurations, or lens parameters available in the lens were not evaluated in significant numbers.

CONTRAINDICATIONS (Reasons not to use)

Do not use DAILIES® (nelfilcon A) One-Day Contact Lenses when any of the following conditions exist:

• Any active corneal infection (bacterial, fungal, or viral).
• Any systemic disease which may be exacerbated by or interferes with contact lens wear:
  • Corneal hypoxia (reduced oxygen to the cornea).
  • Any systemic disease that may interfere with contact lens wear:
  • Corneal hypoesthesia (reduced corneal sensitivity).
• Insufficiency of lacrimal secretion (dry eye) that interferes with contact lens wear:
  • Any condition associated with contact lens wear, intolerance or abnormal ocular response leading to loss of vision.

PRECAUTIONS

Special Precautions for the Eye Care Professional

Front
A one-month study was conducted for the purpose of evaluating the performance for DAILIES Acuvue Contact Lens. Subjective performance measures were evaluated by having the subjects rate these attributes on a scale from 1 to 10, with 10 being "excellent" and 1 being "poor". Results showed that DAILIES Acuvue Contact Lens was statistically different from the baseline lenses collected from the pre-study lenses. As in this study, individual results may vary.


DAILIES® Acuvue Contact Lens

A one-month study was conducted for the purpose of evaluating the performance for DAILIES® Acuvue Contact Lens® lenses. Subjective performance measures were evaluated by having the subjects rate these attributes on a scale from 1 to 10, with 10 being "excellent" and 1 being "poor". Results showed that DAILIES® Acuvue Contact Lens was statistically different from the baseline lenses collected from the pre-study lenses. As in this study, individual results may vary.


Bibliography

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ADVERSE REACTIONS

Potentially serious complications are usually accompanied by one or more of the following signs or symptoms:

- Difficult and/or painful removal of lens
- Excessive watering or other unusual eye secretions including mucopurulent discharge
- Redness of the eye
- Photophobia
- Redness/pain/discomfort/light sensitivity
- Burning, itching, or aching in one or both eyes associated with the use
- Comfort is less compared to when the lens was first placed on eye
- Conjunctival injection
- Blurred vision or halos
- Foreign body sensation or loose foreign object
- Visual distortions or blurring
- Severe discomfort
- Irritation
- Blurred vision or halos
- Visual distortions or blurring
- Foreign body sensation or loose foreign object

ADVERSE REACTIONS CONTINUED

If any of the previous signs or symptoms occur:

- The patient should IMMEDIATELY REMOVING THE LENS. If the discomfort or problem persists, the patient should discard the lens and contact his or her own eye care provider.

- Patients should be advised that serious conditions such as corneal ulcer, infection, corneal vascularization, corneal abrasions, injury, neovascularization or uveitis may be present and may progress rapidly. Patients should be instructed to immediately see an eye care professional at once.

- Patients should be instructed to report any signs or symptoms associated with the use of DAILIES® Acuvue Contact Lens. If a patient experiences any serious adverse effects associated with the use of DAILIES® Acuvue Contact Lens, the patient should immediately discontinue use of the lenses and contact an eye care professional at once.

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