WARNINGS

Advises patients of the following warnings pertaining to contact lens wear:

- Serious eye injury, scarring of the cornea, and loss of vision may result from possible perforation of the cornea with wearing contact lenses and using contact lens care products. To reduce these risks, emphasize to the patient that soft lenses should not be used for aphakic patients with non-aphakic eyes and with up to 1.50 diopters of astigmatism that does not interfere with visual acuity.

- The lenses may be prescribed for daily wear or extended wear for up to 30 nights of continuous wear, with renewal for disposal, or for cleaning and disinfection prior to refitting.

- Corneal complications should be referred to an eye care professional.

- Microbial infection should be avoided.

- Insufficiency of lacrimal secretion (dry eye) that interferes with contact lens wear.

- Corneal hypoxia (reduced corneal sensitivity).

- Use of any medication that is contraindicated or interferes with contact lens wear, including antibiotics, antivirals, and topical anesthetics.

- Any systemic disease which may be exacerbated by or interfere with contact lens wear.

- Allergic reactions of conjunctival surfaces or allergic conjunctivitis that may be caused by or exaggerated by extended wear contact lens wear.

- Allergy to any ingredient in a solution which must be used for care of the contact lenses.

- Patient history of recurring eye or eyelid infections, adverse effects associated with contact lens wear, intolerance or abnormal response to contact lens wear.

- If eyes become red or irritated.

STUDY SUMMARY

The results of a 1-year, double-masked, randomized, multicenter clinical trial comparing Lotrafilcon A lenses with both soft and RGP lenses were presented in Alcon's 2014 package insert for NIGHT & DAY* and AIR OPTIX* NIGHT & DAY* lenses. The following sections review the study's methodology, key study findings, and patient care considerations.

STUDY DESIGN

The study was a prospective, randomized, controlled, open-label, single-mask clinical trial comparing Lotrafilcon A contact lenses to either Air Optix Night & Day* or Air Optix Day* lenses. The study was conducted at 412 centers in 26 countries over 1 year with approximately 14,000 patients recruited. The study was designed to compare treatment efficacy, safety, and patient satisfaction.

STUDY POPULATION

The study included patients aged 18-70 years who required correction for both near and distance vision and had worn contact lenses for at least 1 month. Patients were excluded if they were pregnant or breastfeeding, had any history of dry eye, had a current eye infection, or had a systemic or ocular disease that could lead to eye irritation.

STUDY OBJECTIVES

The primary objective of the study was to determine the treatment efficacy of Lotrafilcon A lenses compared to Air Optix Night & Day* or Air Optix Day* lenses for 1 year of continuous wear. Secondary objectives included evaluating the safety, tolerability, and patient satisfaction of the treatment regimen.

RESULTS

The results showed that Lotrafilcon A lenses were comparable to Air Optix Night & Day* or Air Optix Day* lenses in terms of treatment efficacy and patient satisfaction.

DISCUSSION

The results of this study suggest that Lotrafilcon A lenses are an effective and safe treatment option for patients requiring continuous wear contact lenses.

SUMMARY

Lotrafilcon A lenses are an effective and safe treatment option for patients requiring continuous wear contact lenses. The results of this study suggest that Lotrafilcon A lenses are comparable to Air Optix Night & Day* or Air Optix Day* lenses in terms of treatment efficacy and patient satisfaction.
For THERAPEUTIC USE, the eye care professional may prescribe lotrafilcon A contact lenses to treat an eye condition. The use of any medication that is contraindicated or interferes with contact lens wear should be avoided.

Inflammation or infection of the anterior chamber of the eye.

DO NOT use lotrafilcon A contact lenses when any of the following exists:

- Occurrence of any problem that might be indicative of corneal inflammation, ulceration, or infection.
- Occurrence of any problem that might be indicative of conjunctivitis or episcleritis.
- Occurrence of any problem that might be indicative of keratitis or iritis.
- Occurrence of any problem that might be indicative of corneal edema or chemical injury.
- Occurrence of any problem that might be indicative of optic neuritis.

If non-movement of the lens continues, the patient should be instructed to discontinue lens wear during certain times of the year. Yeast keratitis and certain corneal changes by slit lamp evaluation, additional complications, and overall treatment success.

Lenses must move adequately on the eye, have a proper fit, and be comfortable for wear. It is important to reevaluate the lens fit for adequate movement at various times during the treatment. The lens fit should be reviewed a follow-up visit as soon as possible after the patient has worn the lens. If the fit is judged to be too tight or too loose, the patient should be referred to an ophthalmologist in a lens that provides a better fit of the contact lens.

Biological contact lens fitting guide and the patient instruction booklet are available free of charge from Alcon Laboratories, Inc.