HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ACUVUE® Theravision™ with Ketotifen Contact Lenses safely and effectively. See full prescribing information for ACUVUE® Theravision™ with Ketotifen Contact Lenses.

ACUVUE® Theravision™ with Ketotifen Contact Lenses (etafilcon A with ketotifen daily disposable contact lens)

INDICATIONS AND USAGE

ACUVUE® Theravision™ with Ketotifen Contact Lenses is a daily disposable contact lens for correcting refractive ametropia (myopia and hyperopia) in phakic or aphakic patients who are suitable for contact lens wear and experience ocular allergic itch due to allergic conjunctivitis and who do not have red eye(s) or more than 1.00 D of astigmatism.

The lens contains an H1 histamine receptor antagonist for the prevention of itch associated with allergic conjunctivitis experienced by contact lens users to promote comfortable contact lens wear. The prevention of itch has been demonstrated to last through 12 hours in clinical trials; however, the lens may be worn for longer than 12 hours for vision correction. (2)

Pediatrics (12 years of age and older): The safety and efficacy of ACUVUE® Theravision™ with Ketotifen in pediatric patients has been established.

Pediatrics (under 12 years of age): The safety and efficacy of ACUVUE® Theravision™ with Ketotifen in pediatric patients has not been established.

DOSAGE AND ADMINISTRATION

- Insert one lens per eye per day. (3)
- No more than one ACUVUE® Theravision™ with Ketotifen per eye per day should be used. (3)
- If prevention or relief from itching is needed beyond twelve hours, remove ACUVUE® Theravision™ with Ketotifen and consult your eye care professional. (3)
- ACUVUE® Theravision™ with Ketotifen may be worn beyond twelve hours for vision correction. Lenses should be removed prior to sleeping. (3)

DOSAGE FORMS AND STRENGTHS

etafilcon A daily disposable contact lens with ketotifen (0.019 mg per lens) (4)

CONTRAINDICATIONS

- Red or irritated eye(s); Remove contact lens immediately if eye(s) become red while wearing (5)
- Acute or subacute inflammation or infection of the anterior segment of the eye (5)
- Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids (5)
- Severe insufficiency of lacrimal secretion (5)
- Corneal hypoesthesia (5)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses (5)
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses (5)
- Any active corneal infection (bacterial, fungal, protozoal or viral) (5)
- Known hypersensitivity to any ingredient in this product (5)
- Narrow angle glaucoma (5)

WARNINGS AND PRECAUTIONS

- This product should not be used to treat red eye(s). Remove lenses immediately if the eyes become red or irritated. (6.1)
- Problems with contact lenses could result in serious injury to the eye such as corneal ulcers and lead to loss of vision. (6.2)
- DO NOT use to treat or prevent lens-related irritation/ discomfort (6.3)
- Exposing contact lenses to water during swimming or while in a hot tub may increase the risk of eye infection from microorganisms. (6.5)
- Eye drops containing benzalkonium chloride should not be used simultaneously with this product. Patients should wait 10 minutes after eye drop application before inserting lenses.

ADVERSE REACTIONS

The most commonly observed ocular adverse reactions in clinical studies, occurring in < 2% of ACUVUE® Theravision™ with Ketotifen treated eyes, were eye irritation, eye pain, instillation site irritation, dry eye, photophobia and mydriasis. (7.1)

The most commonly observed non-ocular adverse reactions in clinical studies, occurring in 3% or less of ACUVUE® Theravision™ with Ketotifen treated subjects, were nasopharyngitis and sinusitis. (7.2)

To report SUSPECTED ADVERSE REACTIONS, contact Johnson & Johnson Vision Care, Inc. at 1-800-843-2020.

See 17 for PATIENT COUNSELING INFORMATION and approved patient labeling.

Revised: January 2021

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

1. SYMBOLS KEY

The following symbols may appear on the label or packaging:

SYMBOL	DEFINITION
	Consult Instructions for Use
	Manufactured by or in
	Date of Manufacture
	Use By Date (expiration date)
	Batch Code
	Sterile Using Steam or Dry Heat
	Single Use
	Protect From Light. Store in carton until use.

2. INDICATIONS AND USAGE

ACUVUE® Theravision™ with Ketotifen is a daily disposable contact lens for correcting refractive ametropia (myopia and hyperopia) in phakic or aphakic patients who are suitable for contact lens wear and experience ocular allergic itch due to allergic conjunctivitis and who do not have red eye(s) or more than 1.00 D of astigmatism.

The lens contains an H1 histamine receptor antagonist for the prevention of itch associated with allergic conjunctivitis experienced by contact lens users to promote comfortable contact lens wear. The prevention of itch has been demonstrated to last through 12 hours in clinical trials; however, the lens may be worn for longer than 12 hours for vision correction.

Pediatrics (12 years of age and older): The safety and efficacy of ACUVUE® Theravision™ with Ketotifen in pediatric patients has been established.

Pediatrics (under 12 years of age): The safety and efficacy of ACUVUE® Theravision™ with Ketotifen in pediatric patients has not been established.

3. DOSAGE AND ADMINISTRATION

- Insert one lens per eye per day.
- No more than one ACUVUE® Theravision™ with Ketotifen per eye per day should be used.
- If prevention or relief of itching is needed beyond twelve hours, remove ACUVUE® Theravision™ with Ketotifen and consult your eye care professional.
- ACUVUE® Theravision™ with Ketotifen may be worn beyond twelve hours for vision correction. Lenses should be removed prior to sleeping.
- This lens is not intended to be cleaned or disinfected and should be discarded after a single day's use.

4. DOSAGE FORMS AND STRENGTHS

etafilcon A daily disposable contact lens with ketotifen (0.019 mg per lens).

5. CONTRAINDICATIONS

DO NOT USE ACUVUE® Theravision™ with Ketotifen when any of the following conditions exist:

- Red or irritated eye(s); Remove contact lens immediately if eye(s) become red while wearing
- Narrow angle glaucoma
- Acute or subacute inflammation or infection of the anterior segment of the eye

- Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses
- Any active corneal infection (bacterial, fungal, protozoal or viral)
- Known hypersensitivity to any ingredient in this product

6. WARNINGS AND PRECAUTIONS

6.1 Ocular Redness

This product should not be used to treat red eye(s). Remove lens(es) immediately if the eye(s) become red or irritated.

6.2 Risk of Developing Corneal Ulcers

Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. Clinical study results indicate the following:

When daily wear users wear their lenses overnight, the risk of ulcerative keratitis is greater than among those who do not wear them overnight. Contact lens wearers who are smokers have a higher incidence of corneal ulcers than nonsmokers[1].

6.3 Other Lens-Related Complications

Problems with contact lenses could result in serious injury to the eye(s). If patients experience any of the following, the lens(es) should be IMMEDIATELY REMOVED.

- Transient burning or stinging may be experienced upon instillation [*See Ocular Adverse Reactions* (6.1)]. If burning or stinging persists, the lens(es) should be removed
- Foreign body sensation
- Temporary ocular impairment due to peripheral infiltrates, peripheral corneal ulcers or corneal erosion
- Other physiological observations, such as local or generalized corneal edema, corneal neovascularization, corneal staining, conjunctival injection, tarsal abnormalities, iritis and conjunctivitis, some of which are clinically acceptable in low amounts
- Excessive watering or unusual eye secretions including mucopurulent discharge
- Poor visual acuity, blurred vision, rainbows or halos around objects, feeling of dryness or photophobia

This product should not be used to treat or prevent lens-related symptoms including irritation, discomfort or redness.

6.4 UV Exposure

- Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV blocking contact lenses reduces the risk of developing cataracts or other eye disorders.

- UV absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear, such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. Patients should continue to use UV absorbing eyewear as directed.

6.5 Other Special Precautions

- Not all refractive powers, design configurations, or lens parameters available were tested in clinical investigation of the lenses. Therefore, when selecting an appropriate lens design, the Eye Care Professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness and optic zone diameter. The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction and prevention of itching associated with allergic conjunctivitis; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing Eye Care Professional.
- Eye Care Professionals should instruct the patient to always have a functional pair of spectacles with a current prescription available to use if the patient becomes unable to wear contact lenses, or in circumstances where contact lens wear is not advised.
- **DO NOT** use contact lens cleaning or disinfecting solutions with this product.
- Eye drops containing benzalkonium chloride should not be used simultaneously with this product. Patients should wait 10 minutes after eye drop application before inserting lenses.
- ACUVUE® Theravision™ with Ketotifen is not indicated for overnight wear and should be removed and discarded prior to sleeping.
- Do not expose contact lenses to water while wearing them. Water can harbor microorganisms that can lead to severe infection, vision loss, or blindness. If lenses have been submersed in water when participating in water sports or swimming in pools, hot tubs, lakes, or oceans, the patient should be instructed to discard them and replace them with a new pair. The Eye Care Professional should be consulted for recommendations regarding wearing lenses during any activity involving water.

7. ADVERSE REACTIONS

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a product cannot be directly compared to rates in the clinical trials of another product and may not reflect the rates observed in practice.

7.1 Ocular Adverse Reactions

The most commonly observed ocular adverse reactions in clinical studies, occurring in < 2% of ACUVUE® Theravision™ with Ketotifen treated eyes, were eye irritation, eye pain, instillation site irritation, dry eye, photophobia and mydriasis.

7.2 Non-ocular Adverse Reactions

The most commonly observed non-ocular adverse reactions in clinical studies, occurring in 3% or less of ACUVUE® Theravision™ with Ketotifen treated subjects, were nasopharyngitis and sinusitis.

Other potential lens related adverse reactions are discussed in greater detail in other sections of the label:

- Risk of Developing Corneal Ulcers [see *Warnings and Precautions* (5.2)]
- Other Lens Related Complications [see *Warnings and Precautions* (5.3)]

8. USE IN SPECIFIC POPULATIONS

8.1. Pregnancy

Oral treatment of pregnant rabbits during organogenesis with 45 mg/kg/day of ketotifen [30,000 times the maximum recommended human ocular dose (MRHOD)] resulted in an increased incidence of retarded ossification of the sternebrae. However, no effects were observed in rabbits treated with up to 15 mg/kg/day (10,000 times the MRHOD). Similar treatment of rats during organogenesis with 100 mg/kg/day of ketotifen (66,667 times the MRHOD) did not reveal any biologically relevant effects. In the offspring of the rats that received ketotifen orally from day 15 of pregnancy to day 21 post partum at 50 mg/kg/day (33,333 times the MRHOD), a maternally toxic treatment protocol, the incidence of postnatal mortality was slightly increased, and body weight gain during the first four days post partum was slightly decreased.

8.2. Nursing Mothers

Ketotifen fumarate has been identified in breast milk in rats following oral administration. It is not known whether topical ocular administration could result in sufficient systemic absorption to produce detectable quantities in breast milk. Because many drugs are excreted in human milk, caution should be exercised when etafilcon A with ketotifen is worn by a nursing woman.

8.3. Geriatric Use

Clinical studies of etafilcon A with ketotifen did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

8.4. Pediatrics (under 12 years of age)

The safety and efficacy of ACUVUE® Theravision™ with Ketotifen in pediatric patients has not been established.

9. DESCRIPTION

ACUVUE® Theravision™ with Ketotifen is a sterile, soft (hydrophilic), spherical etafilcon A daily disposable contact lens containing ketotifen, an H_1 receptor antagonist, for topical administration to the eyes.

Ketotifen fumarate is a white to brownish-yellow, fine crystalline powder with a molecular formula of $C_{19}H_{19}NOS \cdot C_4H_4O_4$ and formula weight of 425.50 g/mol. The buffered packaging solution of ACUVUE® Theravision™ with Ketotifen has a pH of 6.6 to 7.1 and an osmolality of not more than 460 mOsm/Kg.

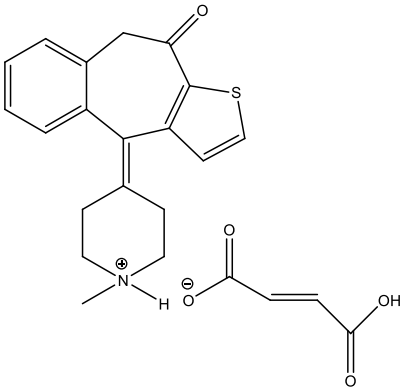
Contains:

Active: ketotifen 0.019 mg per lens

Inactives: boric acid, calcium hydroxide, pentetic acid, sodium chloride, sodium borate, and water.

Chemical Name: 10*H*-Benzo[4,5]cyclohepta[1,2-b]thiophen-10-one, 4,9-dihydro-4-(1-methyl-4-piperidinylidene)-, hydrogen fumarate.

Structural Formula:



This product is preservative free.

The contact lens material (etafilcon A) is a copolymer of 2-hydroxyethyl methacrylate and methacrylic acid cross-linked with 1, 1, 1-trimethylol propane trimethacrylate and ethylene glycol dimethacrylate. ACUVUE® Theravision™ with Ketotifen contact lenses are tinted blue using blue 2-hydroxyethyl methacrylate to make the lenses more visible for handling. A benzotriazole UV absorbing monomer is used to block UV radiation.

Physical/Optical Properties of the Lens:

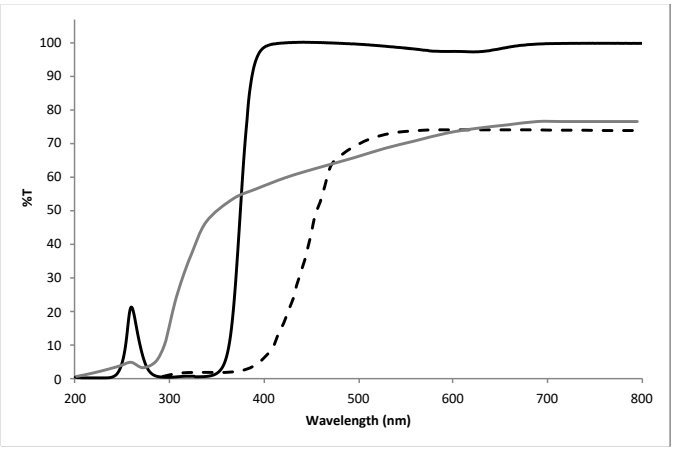
Refractive Index:	1.40
Visible Light Transmission:	90% minimum
Ultraviolet Light Tranmission: (316 nm to 380 nm) UVA	30% maximum
Ultraviolet Light Tranmission: (280 nm to 315 nm) UVB	5% maximum
Surface Character:	Hydrophilic
Water Content:	59%
Oxygen Permeability:	21.4 x 10^{-11}(cm^2/sec) (ml O_2/ml x mmHg) at 35°C (boundary corrected, edge corrected)

Dimensional Properties of the Lens:

Diameter:	14.2 mm
Center Thickness:	-12.00 D: 0.084 mm (varies with power) +6.00 D: 0.230 mm (varies with power)
Base Curve:	8.5 mm and 9.0 mm
Power:	-12.00 D to +6.00 D

Transmittance Curve

etafilcon A with ketotifen, 24 yr. old human cornea[2] and 25 yr. old human crystalline lens[3]



—— etafilcon A with Ketotifen Daily Disposable Contact Lens with Visibility Tint and UV Blocking Capabilities*

…… 25 Yr Old Human Crystalline Lens

—— 24 Yr Old Human Cornea

*The data was obtained from measurements taken through the central 3-5 mm portion of the lens (-3.00D etafilcon A with ketotifen lens, 0.070 mm center thickness).

10. CLINICAL PHARMACOLOGY

10.1. Mechanism of Action of Each Component

1. **Device Component** - In its hydrated state, the lens when placed on the cornea, acts as a refracting medium to focus light rays on the retina to correct refractive ametropia for as long as the lens is worn (up to 24 hours while awake).

   The lens also contains a benzotriazole UV absorbing monomer which blocks UV radiation from the cornea.

2. **Drug Component** - Ketotifen fumarate, a benzocycloheptathiophene derivative, is an approved H1 receptor antagonist that also stabilizes mast cells and prevents eosinophil accumulation. This action prevents the onset of ocular allergic itch allowing for continued lens wear during episodes of allergen exposure and has been demonstrated to last through 12 hours.

11. NONCLINICAL TOXICOLOGY

11.1. Carcinogenesis, Mutagenesis, Impairment of Fertility

Ketotifen fumarate was determined to be non-mutagenic in a battery of *in vitro* and *in vivo* mutagenicity assays including: Ames test, *in vitro* chromosomal aberration test with V79 Chinese hamster cells, *in vivo* micronucleus assay in mouse, and mouse dominant lethal test. In addition, extracts of etafilcon A with ketotifen (0.019mg/lens) prepared in 0.9% sodium chloride or dimethyl sulfoxide were shown to be non-mutagenic in the Ames test. Ketotifen fumarate has demonstrated no carcinogenic effects in lifetime studies in mice and rats at dietary doses more than 70,000 times and 59,000 times the maximum recommended human ocular dose (MRHOD) of 0.0012 mg/kg/day for a 50 kg adult respectively.

Treatment of male rats with oral doses of ketotifen > 10 mg/kg/day orally [8,333 times the MRHOD] for 70 days prior to mating resulted in mortality and a decrease in fertility. Treatment with ketotifen did not impair fertility in female rats receiving up to 50 mg/kg/day of ketotifen orally (41,667 times the MRHOD) for 15 days prior to mating.

11.2. Animal Toxicology and/or Pharmacology

Extracts of etafilcon A with ketotifen (0.019mg/lens) prepared in 0.9% sodium chloride or sesame oil were non-irritating to the rabbit eye. A six month ocular study conducted in New Zealand White Rabbits showed that contact lenses containing 0.019 mg ketotifen per lens or 0.038mg ketotifen per lens were non-irritating and non-toxic to the eye and without systemic toxicity. The lenses were worn for a minimum of 7 hours per day for the duration of the study.

12. CLINICAL STUDIES

In two double-masked, randomized, placebo-controlled human conjunctival allergen challenge (CAC) studies, ACUVUE® Theravision™ with Ketotifen was more effective than placebo (1•DAY ACUVUE®) in preventing ocular itching in patients with allergic conjunctivitis induced by an ocular allergen challenge. ACUVUE® Theravision™ with Ketotifen reduced ocular itching within 3 minutes post conjunctival allergen challenge and the response was sustained for up to 12 hours after lens insertion.

Visual acuity was comparable between ACUVUE® Theravision™ with Ketotifen and *1•DAY* ACUVUE®.

The safety of ACUVUE® Theravision™ with Ketotifen was evaluated in two randomized clinical studies in 491 subjects over a period of 12 weeks.

13. REFERENCES

1. New England Journal of Medicine, September 21, 1989; 321(12), pp. 773-783.
2. Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p. 58, figure 2-21
3. Waxler, M. Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, figure 5

14. HOW SUPPLIED/STORAGE AND HANDLING

14.1 How Supplied

Each UV-absorbing sterile ACUVUE® Theravision™ with Ketotifen (etafilcon A with ketotifen daily disposable contact lens, 0.019 mg/lens) lens is supplied in a foil-sealed plastic package containing a buffered ketotifen solution. The plastic package is marked with base curve, diopter power, diameter, lot number and expiration date.

ACUVUE® Theravision™ with Ketotifen is available in 30 count cartons with the following Lens Parameters:

Base Curve	Diameter	Power Range
Minus		
8.5 mm, 9.0 mm	14.2 mm	-0.50 D to -6.00 D (in 0.25D increments) -6.50 D to -12.00 D (in 0.50D increments)
Plus		
8.5 mm, 9.0 mm	14.2 mm	+0.50 D to +6.00 D (in 0.25D increments)

14.2 Storage and Handling

Store at 15-25°C (59-77°F); with excursions permitted up to 30°C (86°F).

Protect from light – store lenses in carton until use.

15. PATIENT COUNSELING INFORMATION

15.1 Fitting

Conventional methods of fitting contact lenses apply to ACUVUE® Theravision™ with Ketotifen.

15.2 Monovision

Patients who wear ACUVUE® Theravision™ with Ketotifen to correct presbyopia using monovision may not achieve the best corrected visual acuity for either far or near vision. Visual requirements may vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.

15.3 Wearing Schedule (Daily Wear)

- The maximum daily wearing time should be determined by the Eye Care Professional based upon the patient's individual response to contact lenses. Patients tend to over wear the lenses initially. The Eye Care Professional should emphasize the importance of adhering to the initial maximum daily wearing time. Regular checkups, as determined by the Eye Care Professional, are also extremely important.
- ACUVUE® Theravision™ with Ketotifen is intended to be worn once on a daily disposable basis (less than 24 hours, while awake) and should be discarded upon removal. Studies have not been performed to show that ACUVUE® Theravision™ with Ketotifen is safe to wear during sleep.
- Patients should never wear lenses beyond the period recommended by the Eye Care Professional.
- Patients should always discard lenses worn on a daily disposable schedule after the recommended wearing time prescribed by the Eye Care Professional.
- Once ACUVUE® Theravision™ with Ketotifen is discarded, nonmedicated lenses may be worn for the remainder of the day. The patient should not insert a new ACUVUE® Theravision™ with

Ketotifen lens. Only one ACUVUE® Theravision™ with Ketotifen lens may be worn per eye each day.

15.4 Lens Handling and Care

- **DO NOT** use if the sterile blister package is opened or damaged.
- Patients should examine the lens after opening to be sure that it is a single, moist, clean lens that is free of any nicks or tears. If the lens appears damaged, patients should be instructed NOT to use it.
- The Eye Care Professional should review with the patient that no cleaning or disinfection is needed with ACUVUE® Theravision™ with Ketotifen.
- Patients should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her before leaving the Eye Care Professional's office.
- If the lens sticks (stops moving), the patient should be instructed to remove the lens. A few drops of non-preserved sterile saline solution may be applied directly to the eye to assist with removal. If non-movement of the lens continues after a few minutes, the patient should immediately consult the Eye Care Professional.
- Patients should always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup.
- Patients should not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, which causes distorted vision and/or injury to the eye.
- Patients should carefully follow the wearing, handling, application, and removal instructions in the specific "Patient Instruction Guide" pertaining to ACUVUE® Theravision™ with Ketotifen contact lenses and the prescribed wearing schedule.
- Patients should never allow anyone else to wear their lenses. The lenses have been prescribed to fit the patient's eyes and to correct their vision to the degree necessary. Sharing lenses greatly increases the risk of eye infections.
- Patients should always handle lenses carefully and avoid dropping them.
- Patients should avoid all harmful or irritating vapors and fumes while wearing lenses. If aerosol products, such as hair spray, are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Patients should never use tweezers or other tools to remove lenses from the lens container. Instead, patients should remove ACUVUE® Theravision™ with Ketotifen from the blister container packing solution using their fingertips.
- Patients should not touch the lens with fingernails.
- The patient should be advised to never rinse the lenses in water from the tap. Tap water contains many impurities that can contaminate or damage the lenses and may lead to eye infection or injury.

15.5 Concomitant Use of Other Medications

- Patients should always contact the Eye Care Professional before using any medicine in the eyes.
- Certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers and those used for motion sickness, may cause dryness of the eye, increased lens awareness or blurred vision. Should such symptoms exist, proper remedial measures should be prescribed. Depending on the severity, this could include the temporary discontinuance of contact lens wear while such medication is being used.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.
- Eye drops containing benzalkonium chloride should not be used simultaneously with this product. Patients should wait 10 minutes after eye drop application before inserting lenses.

15.6 Other Important Information

- The patient should be instructed to conduct a simple 3-part self-examination at least once a day. They should ask themselves:
  - How do the lenses feel on my eyes?
  - How do my eyes look?
  - Have I noticed a change in my vision?
- If the patient reports any discomfort or problems, he or she should be instructed to IMMEDIATELY REMOVE THE LENS(ES). If the discomfort or problem stops after lens removal, the patient should discard the lens(es) and replace with new non-medicated lens(es). ACUVUE® Theravision™ with Ketotifen should not be worn for the remainder of the day. If the problem continues after inserting new non-medicated lens (es), the patient should remove the lens(es) and IMMEDIATELY CONSULT HIS OR HER EYE CARE PROFESSIONAL.
- The patient should be instructed to not change lens type (e.g. brand name, etc.) or parameters (e.g. diameter, base curve, lens power, etc.) without consulting the Eye Care Professional.
- Instruct patients to always confirm the lens parameters printed on the multi-pack and on the individual lens package match their prescription. If there is a mismatch the patient should not use the product. Patients should inform all doctors (Health Care Professionals) about being a contact lens wearer.
- Patients should always inform their employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- Patients should be advised as to a recommended follow-up schedule. As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes.

15.7 Emergencies

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

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www.acuvue.com

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