



ACUVUE[®]
Theravision[™] with Ketotifen
(etafilcon A lens with 0.019 mg ketotifen)

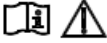







For Eye Allergy Itch

Visibility Tinted with UV Blocking
for Daily Disposable Wear

PATIENT INSTRUCTION GUIDE

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.

WEARING RESTRICTIONS & INDICATIONS

ACUVUE® Theravision™ with Ketotifen are daily disposable contact lenses containing an antihistamine to prevent itchy eyes due to allergies and correcting vision impairments such as nearsightedness (myopia) or farsightedness (hyperopia) in patients suitable for contact lens wear who do not have red eye(s) or more than 1.00D of astigmatism. Itchy eye prevention has been demonstrated to last up to 12 hours in clinical trials; however the lens may be worn for longer than 12 hours for vision correction. Safety and efficacy in patients below the age of 12 years old has not been established.

DO NOT WEAR YOUR LENSES WHILE SLEEPING.

These lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

WARNING: 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. You should continue to use UV absorbing eyewear as directed.

NOTE: 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. Consult your Eye Care Professional for more information.

The ACUVUE® Theravision™ with Ketotifen described in this booklet are prescribed by your Eye Care Professional for daily disposable wear and are to be discarded after each removal. You should:

- Insert one lens per eye per day.

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

WHEN LENSES SHOULD NOT BE WORN (CONTRAINDICATIONS)

DO NOT USE these lenses when you have any of the following conditions:

- Red or irritated eye(s). Remove contact lens(es) immediately if eye(s) become red while wearing;
- Inflammation or infection in or around the eye or eyelids
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Any previously diagnosed condition that makes contact lens wear uncomfortable
- Severe dry eye
- Reduced corneal sensitivity
- Any systemic disease that may affect the eye or be made worse by wearing contact lenses
- Allergic reactions on the surface of the eye or surrounding tissues that may be induced or made worse by wearing contact lenses
- Any active eye infection
- Known hypersensitivity to any ingredient in this product.
- Narrow angle glaucoma

WARNINGS

What You Should Know About Contact Lens Wear:

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION. IF YOU EXPERIENCE:

- **Eye Discomfort,**
- **Excessive Tearing,**
- **Vision Changes,**
- **Loss of Vision,**
- **Eye Redness, or**

- **Other Eye Problems,**

YOU SHOULD IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT YOUR EYE CARE PROFESSIONAL.

- These lenses should not be used to treat red eye(s). Remove lens(es) immediately if your eyes become red or irritated.
- Lenses prescribed for daily disposable wear (i.e., your Eye Care Professional instructs you to remove and discard your lenses at the end of each day), should not be worn while sleeping. Clinical studies have shown the the risk of serious eye problems is increased when lenses are worn overnight.¹
- Studies have shown that contact lens wearers who smoke have a higher rate of eye problems than nonsmokers.
- Problems with contact lenses or lens care products could result in serious injury to the eye.
- Proper use and care of your contact is essential for the safe use of these products.

The overall risk of serious eye problems may be reduced by carefully following directions for lens care.

¹New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783

Specific Instructions for Use and Warnings:

- **Water Activity**

Instruction for Use

Do not expose your contact lenses to water while you are wearing them.

WARNING:

Water can harbor microorganisms that can lead to severe infection, vision loss, or blindness. If your lenses have been submersed in water when participating in water sports or swimming in pools, hot tubs, lakes, or oceans, you should discard them and replace them with a new pair. Ask your Eye Care Professional for recommendations about wearing your lenses during any activity involving water.

PRECAUTIONS

For your eye health, it is important to carefully follow the handling, insertion, removal, and wearing instructions in this booklet, as well as those prescribed by your Eye Care Professional (see **“Lens Handling & Insertion”**, **“Lens Wearing”** and **“Caring for your Lenses”** sections).

General Precautions:

- **Do Not** use contact lens care solutions with this product
- If you wear your contact lenses to correct presbyopia using monovision you **may not** be able to get the best corrected visual acuity for either far or near vision. Visual needs are different for different people, so your Eye Care Professional should work with you when selecting the most appropriate type of lens for you.
- **Always** contact your Eye Care Professional before using any medicine in your eyes.

- **Be aware** that certain medications, such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, oral contraceptives, and those for motion sickness may cause dryness of the eye, increased lens awareness (feeling of the lens in the eye), or blurred vision. Always inform your Eye Care Professional if you experience any problems with your lenses while taking such medications.
- **Do not** change lens type (e.g. brand name, etc.) or parameters (e.g. diameter, base curve, lens power, etc.) without consulting your Eye Care Professional.
- Consult your Eye Care Professional or Health Care Provider if you are pregnant or nursing a baby.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. Ask your Eye Care Professional about the recommended follow-up schedule.

Who Should Know That You are Wearing Contact Lenses:

- **Inform** all of your doctors (Health Care Professionals) about being a contact lens wearer.
- **Always** inform your employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that you not wear contact lenses.

**ADVERSE REACTIONS
(POSSIBLE PROBLEMS WITH LENS WEAR AND WHAT TO DO)**

Possible Problems

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

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

Other potential lens related side effects are discussed in greater detail in other sections of this guide:

Risk of Developing Corneal Ulcers (See WARNINGS)

Other Contact Lens Related Problems

Be aware that problems can occur while wearing contact lenses and may be associated with the following symptoms:

- burning, stinging, itchy, and/or dry eyes
- reduced lens comfort
- feeling of something in your eye (foreign body, scratched area)
- swelling or inflammation in or around the eyes
- eye redness
- eyelid problems
- watery eyes and/or unusual eye secretions
- poor vision

- blurred vision
- rainbows or halos around objects
- sensitivity to light (photophobia)

When any of the above symptoms occur, a serious eye condition may be present. You should **immediately be seen by your Eye Care Professional**, so that the problem can be identified and treated, if necessary, in order to avoid serious eye damage.

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

Recognizing Problems and What To Do

You should conduct a simple 3-part self-examination at least once a day. Ask yourself:

- How do the lenses feel on my eyes?
- How do my eyes look?
- Have I noticed a change in my vision?

If you notice any problems, you should **IMMEDIATELY REMOVE YOUR LENS AND CONTACT YOUR EYE CARE PROFESSIONAL**.

LENS HANDLING AND INSERTION

For your eye health, it is important to carefully follow the handling, insertion, removal, and wearing instructions in this booklet, as well as those prescribed by your Eye Care Professional. If you will not or cannot always follow the recommended care procedures, you should not attempt to wear contact lenses.

When you first get your lenses, be sure that you are able to put the lenses on and remove them (or have someone else available who can remove the lenses for you) before leaving your Eye Care Professional's office.

Step 1: Getting Started

It is essential that you learn and use good hygiene in the care and handling of your new lenses.

Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean, dry, and free of any soaps, lotions, or creams before you handle your lenses.

Before you start:

- Always wash your hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching your lenses.
- You should avoid the use of soaps containing cold cream, lotion, or cosmetics before handling your lenses. These substances may come into contact with the lenses and interfere with successful wearing. It is best to put on your lenses before putting on makeup.

Step 2: Opening the Packaging

Multi-pack

Always confirm the lens parameters (e.g. diameter (DIA), base curve (BC), lens power (D), etc.) printed on the multi-pack and on the individual lens package match your prescription. DO NOT use if there is a mismatch.

Each multi-pack contains individually packaged lenses. Each lens comes in its own lens package designed specifically to keep it sterile while sealed.

Lens Package

DO NOT use if the sterile blister package is opened or damaged.

To open an individual lens package, follow these simple steps:

1. Shake the lens package and check to see that the lens is floating in the solution.
2. Carefully peel back the foil closure to reveal the lens.
3. Place a finger on the lens and slide the lens up the side of the bowl of the lens package until it is free of the container.

Occasionally, a lens may stick to the inside surface of the foil when opened, or to the plastic package itself. This will not affect the sterility of the lens. It is still perfectly safe to use. Carefully remove and inspect the lens following the handling instructions.

Lens Handling Tips

- Handle your lenses with your fingertips, and be careful to avoid contact with fingernails. It is helpful to keep your fingernails short and smooth.
- Develop the habit of always working with the same lens first to avoid mix-ups.
- After you have removed the lens from the packaging, examine it to be sure that it is a single, moist, clean lens that is free of any nicks or tears. If the lens appears damaged, DO NOT use it.

Step 3: Placing the Lens on the Eye

Remember, always start with the same eye.

Once you have opened the lens package, removed, and examined the lens, follow these steps to insert the lens into your eye:

1. BE SURE THE LENS IS NOT INSIDE-OUT by following one of the following procedures:
 - Place the lens on the tip of your index finger and check its profile. The lens should assume a natural, curved, bowl-like shape. If the lens edges tend to point outward, the lens is inside out.
 - Gently squeeze the lens between the thumb and forefinger. The edges should turn inward. If the lens is inside out, the edges will turn slightly outward.

OR

- Place the lens on the tip of your index finger and, looking up at the lens, locate the numbers 1-2-3. 1-2-3 indicates correct orientation, while a reverse of 1-2-3 indicates the lens is inside out. If the lens is inside out (reverse 1-2-3), invert the lens and locate the numbers again to confirm correct lens orientation.
2. With the lens on your index finger, use your other hand to hold your upper eyelid so you won't blink.
3. Pull down your lower eyelid with the other fingers of your "inserting" hand.
4. Look up at the ceiling and gently place the lens on the lower part of your eye.

5. Slowly release your eyelid and close your eye for a moment.
6. Blink several times to center the lens.
7. Use the same technique when inserting the lens for your other eye.

There are other methods of lens placement. If the above method is difficult for you, ask your Eye Care Professional for an alternate method.

Step 4: Checking Your Lenses

After you have successfully inserted your lenses, you should ask yourself:

- Do I see well?
- How do the lenses feel on my eyes?
- How do my eyes look?

If after placement of the lens, your vision is blurred, check for the following:

- The lens is not centered on the eye (see “*Step 5: Centering the Lens,*” next in this booklet).
- If the lens is centered, remove the lens (see “*Removing Your Lenses*”) and check for the following:
 - Cosmetics or oils on the lens. Dispose of the lens and insert a new fresh lens.
 - The lens is on the wrong eye.
 - The lens is inside out (it would also not be as comfortable as normal). See “*Step 3: Placing the Lens on the Eye.*”

If you find that your vision is still blurred after checking the above possibilities, remove the lens and consult your Eye Care Professional.

Note: If a lens is noticeably uncomfortable upon insertion or becomes less comfortable than when it was first inserted, remove the lens immediately and contact your Eye Care Professional. If your examination of your eyes and the lenses shows any other problems, IMMEDIATELY REMOVE YOUR LENSES AND CONTACT YOUR EYE CARE PROFESSIONAL.

Step 5: Centering the Lens

A lens, which is on the cornea (center of your eye), will very rarely move onto the white part of the eye during wear. This, however, can occur if insertion and removal procedures are not performed properly. To center a lens, follow either of these procedures:

- Close your eyelids and gently massage the lens into place through the closed lids.
- OR**
- Gently move the off-centered lens onto the cornea (center of your eye) while the eye is opened using finger pressure on the edge of the upper lid or lower lid.

LENS WEARING

While wearing your lenses, remember the following important precautions:

Hazardous Conditions

- If you use aerosol (spray) products, such as hair-spray, while wearing lenses, keep your eyes closed until the spray has settled.
- **Avoid** all harmful or irritating vapors and fumes while wearing lenses.
- **Never** rinse your lenses in water from the tap. Tap water contains many impurities that can contaminate or damage your lenses and may lead to eye infection or injury.

Water Activity

- Do not expose your contact lenses to water while you are wearing them.

Lubricating/Rewetting Solutions

- Lubricating/Rewetting Solutions should not be used with these lenses. If the lens sticks (stops moving), a few drops of non-preserved sterile saline may be applied to assist with removal.
- **Do not** use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.

Sharing Lenses

- **Never** allow anyone else to wear your lenses. Sharing lenses greatly increases the chance of eye infections.

Adhering to the Prescribed Wearing & Replacement Schedules

- **Never** wear your lenses beyond the amount of time recommended by your Eye Care Professional. Never wear more than one lens per day.
- **Always throw away** worn lenses as prescribed by your Eye Care Professional.

REMOVING YOUR LENSES

CAUTION: Always be sure the lens is on the cornea (center of your eye) before attempting to remove it. Determine this by covering the other eye. If vision is blurred, the lens is either on the white part of the eye or it is not on the eye at all. To locate the lens, inspect the upper area of the eye by looking down into a mirror while pulling the upper lid up. Then inspect the lower area by pulling the lower lid down.

1. Wash, rinse, and dry your hands thoroughly. You should follow the method that is recommended by your Eye Care Professional. Below is an example of one method: the Pinch Method.

Pinch Method:

Step 1. Look up, slide the lens to the lower part of the eye using the forefinger.

Step 2. Gently pinch the lens between the thumb and forefinger.

Step 3. Remove the lens.

2. Follow the instructions in the next section, “*Caring for Your Lenses*”.

NOTE: For your eye health, it is important that the lens moves freely on your eye. If the lens sticks (stops moving) on your eye, apply a few drops of the recommended rewetting solution. Wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues, you should immediately consult your Eye Care Professional.

CARING FOR YOUR LENSES

Remember, there is no cleaning or disinfection needed with these lenses. Always dispose of lenses when they are removed and have replacement non-medicated lenses or glasses available. Any unused product or waste material should be disposed of in accordance with local requirements.

Lens Storage:

- Store these lenses at room temperature
- These lenses are sensitive to light – store individual blister packages in the carton until use.

EMERGENCIES

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes: **FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT YOUR EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM RIGHT AWAY.**

INSTRUCTIONS FOR THE PRESBYOPIC PATIENT

The decision to be fit with monovision correction is most appropriately left to your Eye Care Professional, in conjunction with you, after carefully considering and discussing your needs.

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Revision Date: 03/2021

Revision number: AT-07-20-01