Indication

• ZIRGAN® is indicated for the treatment of eye ulcers caused by a herpes virus

Important Safety Information about ZIRGAN®

• ZIRGAN® is indicated for topical ophthalmic use in the eye only
• Patients should not wear contact lenses if they have signs or symptoms of eye infections while using ZIRGAN®
• The most common side effects reported in patients were blurred vision, eye irritation, eye redness and punctate keratitis (a specific type of eye surface irritation)
• Safety and efficacy in children below the age of 2 years have not been established
• Patients should consult their doctor if they experience pain, redness, itching, or swelling of the eye when using ZIRGAN®

Please see complete information about ZIRGAN® in the accompanying full prescribing information provided in the kit.
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What is herpetic keratitis (eye ulcers)?

• Herpetic keratitis is a recurrent (keeps returning) viral infection of the eye that is caused by the herpes simplex virus (HSV)\(^1\)

• There are 2 major types of HSV: type 1 and type 2\(^2\)
  – HSV-1, the most common type, causes eye infections. It mostly infects the face, causing the familiar cold sore or fever blister
    - Most people—about 90% of people in the United States—are exposed to HSV-1, usually during childhood
  – HSV-2 is the sexually transmitted form of herpes, infecting the genitals

• HSV can infect different areas of the eye. However, it typically affects the cornea. This type of infection is called herpetic keratitis\(^2\)

Why is it important to treat herpetic keratitis?

• Herpetic keratitis should not be ignored. If it is not treated, it may lead to blindness or other complications\(^3\)

• Herpetic keratitis can scar the cornea, making it difficult to see. A person with a scarred cornea may need to have a corneal transplant in order to see clearly again\(^4\)

• For these reasons, it is very important to follow your doctor’s instructions regarding treatment
Why do I have herpetic keratitis?

• You are not alone. More than 500,000 people in the United States have some type of HSV-related eye disease.³
  – Each year there are 20,000 new cases and 28,000 reactivations
• In fact, nearly everyone (90% of the US population) is exposed to HSV-1, usually in childhood²
• It is thought that the strain (type) of HSV or a patient’s immune system may play a role⁵
• Because HSV-1 is passed on through contact with infected oral discharge or sores, crowded conditions may play a role in infection⁶
• Even though most people have been exposed to HSV-1 early in life, it is unclear why some people get eye ulcers and others do not²⁵

DID YOU KNOW?

Herpetic keratitis is the leading infectious cause of corneal blindness in the United States.¹

Words in blue are defined in the back of this brochure.

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1. Infection
   - The herpes virus enters the body through direct contact with either the skin or mucous membranes, such as the eyes, mouth, or nose
   - Primary HSV-1 infection is often without symptoms but may appear as an upper respiratory infection

2. Spread
   - Once inside the body, the virus spreads from infected cells to nearby nerve endings
   - The virus then becomes latent in the trigeminal ganglion

3. Reactivation
   - Even though symptoms may go away, the herpes virus can stay dormant in the nerves
   - Reactivation can be triggered by several things, including:
     - Stress
     - Sun exposure
     - Trauma to the body (such as injury or surgery)
     - Menstruation
     - Certain medications
How HSV infection turns into herpetic keratitis (dendritic ulcers)³

- Corneal vesicles (blisters) can form and erupt several hours after the activated virus infects the eye. A **dendritic** pattern forms when the vesicles group together.
- The dendritic ulcer that forms is herpetic keratitis.

What do dendritic ulcers look like?

**Healthy cornea**  
**Cornea with a dendritic ulcer**

DID YOU KNOW?  
More than 28,000 reactivations of HSV occur in the United States annually.³
What are the symptoms of herpetic keratitis?

• Symptoms may include a painful sore on the eyelid and/or cornea, eye redness, blurred vision, sensitivity to light, tearing, and discharge\textsuperscript{1,2}
• Getting an early diagnosis and proper treatment of herpetic keratitis is important because it can lead to corneal blindness\textsuperscript{1}
• Once you have this infection, you have up to a 50\% chance of it coming back\textsuperscript{1}
• See your eye doctor immediately if your symptoms return\textsuperscript{2}

How is herpetic keratitis treated?

• Herpetic keratitis can severely damage your eye if left untreated\textsuperscript{2}
• Treatment is advised to minimize the chances of corneal damage and scarring\textsuperscript{3}
• Treatment of herpetic keratitis depends on its severity\textsuperscript{7}
• \textbf{Antiviral medicine} applied to the eye is the primary way herpetic keratitis is treated\textsuperscript{7}
• Also, your doctor may gently scrape the surface of the eye to remove diseased tissue. This procedure is called corneal debridement\textsuperscript{2}
• In some cases, antiviral medicines taken by mouth are also used\textsuperscript{3}

\begin{center}
\textbf{DID YOU KNOW?}
More than 500,000 people in the United States experience some type of HSV-related eye disease.\textsuperscript{3}
\end{center}
ZIRGAN® (ganciclovir ophthalmic gel) 0.15%—Approved to treat herpetic keratitis

- ZIRGAN® is indicated for the treatment of eye ulcers caused by a herpes virus.
- ZIRGAN® is designed specifically to target the herpes virus-infected cells in the eye, not healthy corneal cells.
- It is important to use ZIRGAN® as prescribed by your eye doctor.

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- Patients should consult their doctor if they experience pain, redness, itching, or swelling of the eye when using ZIRGAN®.

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How to use ZIRGAN®

INSTRUCTIONS:

1. Wash your hands before using ZIRGAN®

2. Do not wear contact lenses if you have an eye infection while using ZIRGAN®

3. Tilt your head back slightly and pull down your lower eyelid to create a small pocket. Hold the dropper above the eye with the tip down.

4. Do not allow the tip of the dropper to touch any surface (including your eye). It may contaminate the gel.

5. ZIRGAN® is a gel that is administered as a drop. Look up and away from the tube as you squeeze out a drop. For best results, gently squeeze the tube of ZIRGAN® from the bottom of the tube toward the tip of the applicator (as you would a tube of toothpaste).

6. Once the drop is administered, close your eye.

7. Gently press your finger to the inside corner of your eye (near your nose) for about 1 minute to prevent the liquid from draining into your tear duct.

DOSING: ZIRGAN® is applied 5 times per day until your eye ulcer heals; then the gel is applied 3 times per day for 7 days. Follow your doctor’s instructions.

STORAGE: Store ZIRGAN® at room temperature (15°C-25°C or 59°F-77°F). Do not freeze.

CONTACT YOUR DOCTOR: If pain develops, or if redness, itching, or swelling become worse, contact your doctor.
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Where can I get more information about herpetic keratitis?

American Academy of Ophthalmology
PO Box 7424
San Francisco, CA 94120-7424
415-561-8500
http://www.aao.org/aao/contact_us.cfm

Centers for Disease Control and Prevention
1600 Clifton Rd
Atlanta, GA 30333
800-CDC-INFO (800-232-4636)
http://www.cdc.gov

Mayo Clinic
13400 E Shea Blvd
Scottsdale, AZ 85259
480-301-8000
http://www.mayoclinic.org/

National Eye Institute
31 Center Dr MSC 2510
Bethesda, MD 20892-2510
301-496-5248
http://www.nei.nih.gov

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The parts of the eye

Definitions of terms

**Anterior chamber**: fluid-filled space inside the eye between the iris and cornea. The anterior chamber is filled with a watery substance called the aqueous humor that maintains the pressure within the eye\textsuperscript{10,11}

**Antiviral medicine**: an agent used to treat viral infections\textsuperscript{12}

**Cornea**: clear part of the outer coat of the eyeball that covers the iris, pupil, and anterior chamber. It helps shield the eye from germs, dust, and foreign material. The cornea also helps focus the entry of light into the eye and accounts for almost two-thirds of the eye’s total focusing power\textsuperscript{10,11}

**Dendritic**: branched like a tree\textsuperscript{12}

**Dormant**: inactive, sleeping

**Iris**: colored part of the eye in front of the lens that controls the amount of light reaching the retina\textsuperscript{11}
**Keratitis**: inflammation (burning and irritation) of the cornea\(^{10,12}\)

**Latent**: dormant, inactive

**Lens**: curved surface of the eye that brings rays of light to a focus in the retina. It can change shape through muscles in the eye to help focus on objects at different distances. The lens accounts for approximately one-third of the eye’s total focusing power\(^{11}\)

**Macula**: small and highly sensitive part of the retina responsible for detailed central vision\(^{10}\)

**Menstruation**: woman’s monthly period\(^{12}\)

**Mucous membranes**: smooth tissues kept moist with secretions\(^{12}\)

**Optic nerve**: nerve that carries visual impulses from the retina to the brain\(^{11}\)

**Primary HSV-1 infection**: an infection that occurs in patients who have never been exposed to the herpes virus\(^3\)

**Punctate**: having dots or points\(^{12}\)

**Pupil**: round hole in the center of the iris that allows light to reach the retina\(^{10}\)

**Respiratory**: having to do with the lungs and breathing\(^{12}\)

**Retina**: light-sensitive layer of receptors and nerves at the back of the eye that converts light into a focused image. The retina contains cells called rods (which produce black-and-white and night vision) and cones (which produce color vision)\(^{10,11}\)

**Trigeminal ganglion**: nerve bundle located at the base of the skull where dormant herpes virus rests until it reactivates\(^3\)

**Virus**: an infectious agent that causes disease by making copies of itself in infected cells\(^3\)

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To contact Bausch + Lomb, call 1-800-323-0000 or visit www.bausch.com.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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