# Patient package insert according to Pharmacists' Regulations (Preparations) -1986 This medicine can be sold with a physician's prescription only

### **ACICLOVIR VISION**

Eye ointment

### Active ingredient:

Each gram contains the active ingredient:

Aciclovir 3% w/w

For information on Inactive ingredients and allergens in the medicine – see section 6 "additional information".

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is the same as yours.

1. What is the medicine intended for?
Aciclovir Vision eye ointment is intended for the treatment of keratitis (inflammation of the cornea of the eye) caused by the herpes simplex virus.

Therapeutic group: Antivirals.

# 2. Before using the medicine:

Do not use the medicine if:

You are sensitive (allergic) to the active substance aciclovir, valaciclovir or any of the other ingredients of this medicine (listed in section 6 "additional information").

Special warnings regarding the use of this medicine: Before using **Aciclovir Vision**, tell your doctor or pharmacist if: you wear contact lenses.

You should avoid wearing contact lenses while using Aciclovir Vision.

If you are not sure, ask your doctor or pharmacist before using Aciclovir Vision.

### Children and adolescents:

No special requirements. Dosage and method of administration as in adults.

### Drug interactions:

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

### Pregnancy, breast-feeding and fertility:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

The use of this medicine during pregnancy will be done according to the doctor's instructions when the potential benefits outweigh the potential risk.

There is no information on the effect of aciclovir on female or male fertility.

### Driving and using machines:

Aciclovir Vision may cause blurred vision and have a transient effect on your vision, therefore caution is recommended when driving and using machines.

As for children, they should be warned of no riding bicycles or playing near the road, etc.

**3. How to use this medicine?** Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine. The dosage and manner of treatment will be determined by the doctor only.

The usual dosage is:
Adults and children:
Aciclovir Vision is applied by squeezing a 1 cm strip of ointment into the lower conjunctival sac (the inner side of the lower eyelid), 5 times daily, approximately 4 hours apart, except when sleeping.

Aciclovir Vision should be applied for at least 3 days after the

symptoms have resolved.

# **Elderly patients:**

There are no special requirements for dose adjustment and method of administration.

Do not exceed the recommended dose.

# Treatment duration:

Use this medicine for the duration of time prescribed by your doctor.

# Method of administration

Do not swallow. Aciclovir Vision is intended for use in the eyes only.

1. Wash your hands before using the medicine

Use your finger to gently pull down the lower eyelid of the infected eye (Diagram 1)

- 3. Gently tilt your head backwards and look up 4. Apply a 1 cm strip of **Aciclovir Vision** on the inner side of the lower eyelid. Make sure the tip of the tube does not touch
- the eye (Diagram 2)
  5. Close your eye for 30 seconds (Diagram 3)

6. Wash your hands after application



Diagram 1

Diagram 2

Diagram 3

# If you have accidentally used a higher dosage

Tell your doctor or pharmacist if you have used more **Aciclovir Vision** than your recommended dose.

If you took a higher dosage or if a child has accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

# If you forget to use the medicine

If you forgot to use the medicine and have missed a dose, take

it as soon as you remember.

However, if it is nearly time for your next application, skip the missed application. Continue as per the usual scheme afterwards.

Do not use a double dose to make up for a forgotten dose. Continue with the treatment as recommended by the

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions on the use of this medicine, consult the doctor or pharmacist.

**4. <u>Side effects</u>**Like any medicine, the use of **Aciclovir Vision** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Very common side effects (may affect more than 1 in 10 patients):

Superficial keratopathy - allergic reaction, which does not require treatment discontinuation and resolves without complications.

- Common side effects (may affect up to 1 in 10 patients):

   Transient mild burning sensation in the eye, which occurs immediately after application.
- conjunctivitis (inflammation of the eye mucosa).

# Rare side effects (may affect up to 1 in 1000 patients): - Blepharitis (inflammation of the eyelid).

Very rare side effects (may affect up to 1 in 10000 patients):

- Allergic reactions: immediate type hypersensitivity reactions, including angioedema (swelling of the face, lips, tongue and throat) and urticaria.

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

### Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking the link "report side effects due to medication" that can be found on the homepage of the Ministry of Health website (<a href="www.health.gov.il">www.health.gov.il</a>) directing to an online form for reporting side effects, or by clicking the link: <a href="https://sideeffects.health.gov.il">https://sideeffects.health.gov.il</a>.

- 5. How to store the medicine?
  Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight
- of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor. Do not use the medicine after the expiry date (exp. Date) stated on the package. The expiry date refers to the last day of that month. of that month.
- This medicine can be used up to 28 days from the day it is first opened and no later than the expiration date shown on the package.
- Storage conditions: Store below 25°C.

  Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6.** Additional information
In addition to the active ingredient, this medicine also contains - Paraffin, white soft.

What does the medicine look like and what does the package contain: An aluminium tube containing 5 grams of white or almost white

Marketing authorization holder and importer RAZ pharmaceutics LTD., 31 GESHER HAETZ ST., INDUSTRIAL PARK, EMEK HEFER, 3877701, ISRAEL

Registration numbers of the medicines in the national drug registry of the ministry of health: 175-52-37211-99.

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