

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Acyclo-V 200 mg tablets

Acyclo-V 400 mg tablets

Acyclo-V 200 - Each tablet contains 200 mg acyclovir

Acyclo-V 400 - Each tablet contains 400 mg acyclovir

Additional ingredients are listed in section 6 and in the "Important information about some ingredients of the medicine" section.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

Acyclo-V contains a medicine called Acyclovir. It acts by killing viruses or stopping their growth.

Acyclo-V can be used for:

- Treatment of Varicella (Chickenpox) and Herpes Zoster (Shingles).
- Treatment of cold sores, genital herpes and other herpes simplex infections.
- Prevention of recurrence of herpes simplex infections in patients with properly functioning immune system.
- Prevention of herpes simplex infections in people whose immune system is compromised, i.e. whose body is less able to fight off infections.

Therapeutic class:Antivirals.

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to acyclovir or valacyclovir or to any of the additional ingredients the medicine contains (listed in section 6).

Do not take **Acyclo-V** if this applies to you. If you are unsure, talk to a pharmacist or to your doctor before taking **Acyclo-V**.

Special warnings regarding the use of the medicine:

Before treatment with Acyclo-V, inform the doctor if:

- You have kidney problems.
- You are over 65 years old.

If you are unsure if these apply to you, talk to a pharmacist or to your doctor before taking **Acyclo-V**.

It is important to drink a lot of water while taking **Acyclo-V**.

Drug-drug interactions:

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

- Probenecid, for treatment of gout.
- Cimetidine, for treatment of gastric ulcers.
- Mycophenolate mofetil, used to prevent your body from rejecting transplanted organs.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you might be pregnant, or planning to become pregnant, consult a doctor before using the medicine.

Driving and operating machinery:

Certain side effects, such as the sensation of drowsiness or sleepiness, may impair your ability to concentrate and react. You should make sure that you are not affected by these effects before driving or operating machinery, and before engaging in any activity that requires alertness.

Important information about some ingredients of the medicine:

This medicine contains less than 23 mg of sodium per tablet, and is therefore considered sodium-free.

Acyclo-V 200 contains lactose. If you have been told by your doctor that you have intolerance to some sugars, consult your doctor before using this medical

preparation.

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The dosage and treatment regimen will be determined by the doctor only.

The dose you need to take depends on the reason for which **Acyclo-V** was prescribed for you. Your doctor will speak to you about it.

Your doctor may adjust Acyclo-V dose for you if:

- It is intended for a child.
- You are over 65 years old.
- You have kidney problems.

Talk to your doctor before taking

Acyclo-V if any of these apply to you.

Do not exceed the recommended dose.

Method of administration

- This medicine should be taken orally.
- The tablet should be swallowed whole with some water.
- The treatment with **Acyclo-V** should be started as soon as possible.

Crushing/halving/chewing:

- Do not chew. The tablet is intended to be swallowed.
- Do not halve the tablet to take a reduced dose, because the dose in each half is not equal. If needed, the tablet may be halved or crushed in order to make swallowing easier, and all parts should be swallowed immediately with water.

If you accidentally take a higher dosage

Acyclo-V usually does not cause any harm, unless you have taken too much of it for a few days.

If you took an overdose or a child accidentally swallowed this medicine, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.

If you forgot to take the medicine

If you forgot to take this medicine at the appointed time, take your dose as soon as you remember. However, if you

remember it close to the time of the next dose, skip the missed dose.

Do not take a double dose in order to compensate for a forgotten dose.

Follow the treatment as recommended by the doctor.

Medicines should not be taken in the dark! Check the label and the dose every time you take the medicine.

Wear glasses if you need them. If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects:

As with any medicine, using **Acyclo-V** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Allergic reactions (may occur in up to 1 out of 1,000 people)

If you have an allergic reaction, **stop taking Acyclo-V and contact the doctor immediately.** The signs may include:

- Rash, itching or hives (itchy bumps) on your skin.
- Swelling of the face, lips, tongue or other parts of your body.
- Shortness of breath, wheezing or breathing difficulties.
- Collapsing.

Additional side effects

Common side effects - side effects that occur in 1-10 out of 100 users

- Headache.
- Feeling of dizziness.
- Nausea or vomiting.
- Diarrhea.
- Abdominal pains.
- Rash.
- Skin reaction following exposure to light (hypersensitivity to light).
- Itching.
- Feeling of tiredness.
- Unexplained fever (high temperature) and a feeling of fainting, especially when rising to stand up.

Uncommon side effects - side effects that occur in 1-10 out of 1,000 users

- Hive-like itchy rash.
- Hair loss.

Rare side effects - side effects that occur in 1-10 out of 10,000 users

- Effects on certain blood and urine tests.
- Elevation of liver enzymes' levels.
- **Very rare side effects - side effects that occur in less than one out of 10,000 patients**
- Decrease in red blood cells count (anemia).
- Decrease in white blood cells count (leukopenia).
- Decrease in the number of platelets (cells that help the blood to clot) (thrombocytopenia).
- Feeling of weakness.
- Feeling of restlessness or confusion.
- Tremors.
- Hallucinations (seeing or hearing non-existing things).
- Seizures.
- Feeling of drowsiness or abnormal sleepiness.
- Loss of balance when walking and loss of coordination.
- Difficulty to speak.
- Inability to think or judge clearly.
- loss of consciousness (coma).
- Paralysis of part or all of your body.
- Abnormal behavior, speech and eye movement.
- Neck stiffness and sensitivity to light.
- Hepatitis.
- Yellowing of the skin and the white part of your eyes (jaundice).

- Kidney problems in which you are urinating less or not at all.
- Lower back pain, in the region where your kidney is located or above your pelvis (renal pain).

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor. Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by

clicking on the following link: <https://sideeffects.health.gov.il/>

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (Exp) appearing on the package. The expiry date refers to the last day of that month.

Storage: Store at a temperature lower than 25°C.

6. Additional information:

In addition to the active ingredient the medicine also contains:

Acyclo-V 200:

Lactose, Microcrystalline Cellulose, Sodium Starch Glycolate, Povidone, Magnesium Stearate.

Acyclo-V 400:

Microcrystalline Cellulose, Sodium Starch Glycolate, Povidone, Magnesium Stearate.

What does the medicine look like and what are the contents of the package:
Acyclo-V 200: Biconvex, white tablets.

Acyclo-V 400: Biconvex, scored, white tablets.

The tablets are supplied in a carton package containing 2, 10, 20, 25, 30, 60, 70 or 100 tablets in a blister.

Not all package sizes may be marketed.

Manufacturer/license holder: CTS Chemical Industries Ltd., Kiryat Malachi
This leaflet from 05/2020 is formatted according to the requirements of the Ministry of Health, and its content matches the leaflet of the original preparation, which was checked and approved by the Ministry of Health in 01/2017.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Acyclo-V 200: 1186228104

Acyclo-V 400: 1186328105