

## PATIENT INFORMATION

### VALACYCLOVIR TABLETS, USP

Read the Patient Information that comes with valacyclovir tablets before you start using it and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. Ask your healthcare provider or pharmacist if you have questions.

#### **What are valacyclovir tablets?**

Valacyclovir tablets are prescription antiviral medicine. Valacyclovir tablets lowers the ability of herpes viruses to multiply in your body.

Valacyclovir tablets are used in adults:

- to treat cold sores (also called fever blisters or herpes labialis)
- to treat shingles (also called herpes zoster)
- to treat or control genital herpes outbreaks in adults with normal immune systems
- to control genital herpes outbreaks in adults infected with the human immunodeficiency virus (HIV) with CD4+ cell count greater than 100 cells/mm<sup>3</sup>
- with safer sex practices to lower the chances of spreading genital herpes to others. Even with safer sex practices, it is still possible to spread genital herpes.

Valacyclovir tablets used daily with the following safer sex practices can lower the chances of passing genital herpes to your partner.

- **Do not have sexual contact with your partner when you have any symptom or outbreak of genital herpes.**
- **Use a condom** made of latex or polyurethane whenever you have sexual contact.

Valacyclovir tablets are used in children:

- to treat cold sores (for children ≥12 years of age)
- to treat chickenpox (for children 2 to <18 years of age).

**Valacyclovir tablets do not cure herpes infections** (cold sores, chickenpox, shingles, or genital herpes).

The efficacy of valacyclovir tablets have not been studied in children who have not reached puberty.

#### **What are cold sores, chickenpox, shingles, and genital herpes?**

**Cold sores** are caused by a herpes virus that may be spread by kissing or other physical contact with the infected area of the skin. They are small, painful ulcers that you get in or around your mouth. It is not known if valacyclovir tablets can stop the spread of cold sores to others.

**Chickenpox** is caused by a herpes virus. It causes an itchy rash of multiple small, red bumps that look like pimples or insect bites usually appearing first on the abdomen or back and face. It can spread to almost everywhere else on the body and may be accompanied by flu-like symptoms.

**Shingles** is caused by the same herpes virus that causes chickenpox. It causes small, painful blisters that happen on your skin. Shingles occurs in people who have already had chickenpox. Shingles can be spread to people who have not had chickenpox or the chickenpox vaccine by contact with the infected areas of the skin. It is not known if valacyclovir tablets can stop the spread of shingles to others.

**Genital herpes** is a sexually transmitted disease. It causes small, painful blisters on your genital area. You can spread genital herpes to others, even when you have no symptoms. If you are sexually active, you can still

pass herpes to your partner, even if you are taking valacyclovir tablets. Valacyclovir tablets, taken every day as prescribed and used with the following **safer sex practices**, can lower the chances of passing genital herpes to your partner.

- Do not have sexual contact with your partner when you have any symptom or outbreak of genital herpes.
- Use a condom made of latex or polyurethane whenever you have sexual contact.

Ask your healthcare provider for more information about safer sex practices.

#### **Who should not take valacyclovir tablets?**

**Do not take valacyclovir tablets** if you are allergic to any of its ingredients or to acyclovir. The active ingredient is valacyclovir. See the end of this leaflet for a complete list of ingredients in valacyclovir tablets.

#### **Before taking valacyclovir tablets, tell your healthcare provider:**

**About all your medical conditions**, including:


- **if you have had a bone marrow transplant or kidney transplant, or if you have advanced HIV disease or “AIDS”.** Patients with these conditions may have a higher chance for getting a blood disorder called thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS). TTP/HUS can result in death.
- **if you have kidney problems.** Patients with kidney problems may have a higher chance for getting side effects or more kidney problems with valacyclovir tablets. Your healthcare provider may give you a lower dose of valacyclovir tablets.
- **if you are 65 years of age or older.** Elderly patients have a higher chance of certain side effects. Also, elderly patients are more likely to have kidney problems. Your healthcare provider may give you a lower dose of valacyclovir tablets.
- **if you are pregnant or planning to become pregnant.** Talk with your healthcare provider about the risks and benefits of taking prescription drugs (including valacyclovir tablets) during pregnancy.
- **if you are breastfeeding.** Valacyclovir hydrochloride may pass into your milk and it may harm your baby. Talk with your healthcare provider about the best way to feed your baby if you are taking valacyclovir tablets.
- **about all the medicines you take**, including prescription and non-prescription medicines, vitamins, and herbal supplements. Valacyclovir tablets may affect other medicines, and other medicines may affect valacyclovir tablets. It is a good idea to keep a complete list of all the medicines you take. Show this list to your healthcare provider and pharmacist any time you get a new medicine.

#### **How should I take valacyclovir tablets?**

Take valacyclovir tablets exactly as prescribed by your healthcare provider. Your dose of valacyclovir tablets and length of treatment will depend on the type of herpes infection that you have and any other medical problems that you have.

- Do not stop valacyclovir tablets or change your treatment without talking to your healthcare provider.
- Valacyclovir tablets can be taken with or without food.
- If you are taking valacyclovir tablets to treat cold sores, chickenpox, shingles, or genital herpes, you should start treatment as soon as possible after your symptoms start. Valacyclovir tablets may not help you if you start treatment too late.
- If you miss a dose of valacyclovir tablets, take it as soon as you remember and then take your next dose at its regular time. However, if it is almost time for your next dose, do not take the missed dose. Wait and take the next dose at the regular time.

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- Do not take more than the prescribed number of valacyclovir tablets each day. Call your healthcare provider right away if you take too much valacyclovir tablets.

**Manufactured by:**  
 Jubilant Generics Limited  
 Roorkee - 247661, India

**What are the possible side effects of valacyclovir tablets?**

**Kidney failure and nervous system problems are not common, but can be serious in some patients taking valacyclovir tablets.** Nervous system problems include aggressive behavior, unsteady movement, shaky movements, confusion, speech problems, hallucinations (seeing or hearing things that are really not there), seizures, and coma. Kidney failure and nervous system problems have happened in patients who already have kidney disease and in elderly patients whose kidneys do not work well due to age. **Always tell your healthcare provider if you have kidney problems before taking valacyclovir tablets. Call your doctor right away if you get a nervous system problem while you are taking valacyclovir tablets.**

Common side effects of valacyclovir tablets in adults include headache, nausea, stomach pain, vomiting, and dizziness. Side effects in HIV-infected adults include headache, tiredness, and rash. These side effects usually are mild and do not cause patients to stop taking valacyclovir tablets.

Other less common side effects in adults include painful periods in women, joint pain, depression, low blood cell counts, and changes in tests that measure how well the liver and kidneys work.

The most common side effect seen in children <18 years of age was headache.

**Talk to your healthcare provider if you develop any side effects that concern you.**

These are not all the side effects of valacyclovir tablets. For more information ask your healthcare provider or pharmacist.

**How should I store valacyclovir tablets?**

- Store at 20°C-25°C (68°F-77°F), excursions permitted to 15°C-30°C (59°F-86°F) [See USP Controlled Room Temperature].
- Store valacyclovir suspension between 2°C to 8°C (36°F to 46°F) in a refrigerator. Discard after 28 days.
- Keep valacyclovir tablets in a well closed container.
- Do not keep medicine that is out of date or that you no longer need.
- Keep valacyclovir tablets and all medicines out of the reach of children.

**General information about valacyclovir tablets**

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use valacyclovir tablets for a condition for which it was not prescribed. Do not give valacyclovir tablets to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about valacyclovir tablets. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about valacyclovir tablets that is written for health professionals.

For more information, call toll free number 1-800-313-4623.

**What are the ingredients in valacyclovir tablets?**

**Active Ingredient:** Valacyclovir Hydrochloride, USP

**Inactive Ingredients:** Crospovidone, FD&C Blue No. 2, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80 and titanium dioxide.


**Marketed by:**  
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