

PATIENT INFORMATION
Valacyclovir Tablets, USP

Read the Patient Information that comes with valacyclovir hydrochloride 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 is valacyclovir hydrochloride ?

Valacyclovir hydrochloride is a prescription antiviral medicine. Valacyclovir hydrochloride lowers the ability of herpes viruses to multiply in your body.

Valacyclovir hydrochloride is 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/mm³
- 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 hydrochloride 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 hydrochloride is 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 hydrochloride does not cure herpes infections (cold sores, chickenpox, shingles, or genital herpes).

The efficacy of valacyclovir hydrochloride has 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 hydrochloride 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 hydrochloride 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 hydrochloride. Valacyclovir hydrochloride, 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 hydrochloride?

Do not take valacyclovir hydrochloride 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 hydrochloride.

Before taking valacyclovir hydrochloride, 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 hydrochloride. Your healthcare provider may give you a lower dose of valacyclovir hydrochloride.
- **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 hydrochloride.
- **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 hydrochloride) 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 hydrochloride.
- **about all the medicines you take,** including prescription and non-prescription medicines, vitamins, and herbal supplements. Valacyclovir hydrochloride may affect other medicines, and other medicines may affect valacyclovir hydrochloride. 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 hydrochloride?

Take valacyclovir hydrochloride exactly as prescribed by your healthcare provider. Your dose of valacyclovir hydrochloride 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 hydrochloride or change your treatment without talking to your healthcare provider.
- Valacyclovir hydrochloride can be taken with or without food.
- If you are taking valacyclovir hydrochloride to treat cold sores, chickenpox, shingles, or genital herpes, you should start treatment as soon as possible after your symptoms start. Valacyclovir hydrochloride may not help you if you start treatment too late.
- If you miss a dose of valacyclovir hydrochloride, 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.
- Do not take more than the prescribed number of valacyclovir hydrochloride tablets each day. Call your healthcare provider right away if you take too much valacyclovir hydrochloride.

What are the possible side effects of valacyclovir hydrochloride?

Kidney failure and nervous system problems are not common, but can be serious in some patients taking valacyclovir hydrochloride. 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 hydrochloride. Call your doctor right away if you get a nervous system problem while you are taking valacyclovir hydrochloride.**

Common side effects of valacyclovir hydrochloride 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 hydrochloride.

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 hydrochloride. For more information ask your healthcare provider or pharmacist.

How should I store valacyclovir hydrochloride?

- Store valacyclovir hydrochloride tablets at room temperature, 20° to 25°C (68° to 77°F).
- Store valacyclovir hydrochloride suspension between 2° to 8°C (36° to 46°F) in a refrigerator. Discard after 28 days.
- Keep valacyclovir hydrochloride in a tightly closed container.
- Do not keep medicine that is out of date or that you no longer need.
- Keep valacyclovir hydrochloride and all medicines out of the reach of children.

General information about valacyclovir hydrochloride

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use valacyclovir hydrochloride for a condition for which it was not prescribed. Do not give valacyclovir hydrochloride 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 hydrochloride. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about valacyclovir hydrochloride that is written for health professionals.

What are the ingredients in valacyclovir hydrochloride?

Active Ingredient: valacyclovir hydrochloride USP (monohydrate)

Inactive Ingredients: crospovidone, FD&C blue #2/ indigo carmine aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, and titanium dioxide.



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