

PATIENT INFORMATION

Valacyclovir (val-a-SYE-kloe-veer) Tablets, USP

What is valacyclovir tablets?

Valacyclovir tablets is a prescription medicine used in adults:

- to treat cold sores (herpes labialis).
- to treat or control genital herpes outbreaks in adults with normal immune systems.
- to control genital herpes outbreaks in adults with human immunodeficiency virus-1 (HIV-1).
- with safer sex practices to lower the chance of spreading genital herpes to others, in adults with normal immune systems. Even with safer sex practices, it is still possible to spread genital herpes.
 - **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.
- to treat shingles (herpes zoster) in adults with normal immune systems.

Valacyclovir tablets is used in children to treat:

- cold sores in children 12 years of age and older.
- chickenpox in children with normal immune systems 2 years of age to less than 18 years of age.

Valacyclovir tablets does not cure cold sores, chickenpox, shingles, or genital herpes.

- It is not known if valacyclovir tablets is safe and effective in people with weakened immune systems, other than for control of outbreaks of genital herpes in people with HIV-1.
- It is not known if valacyclovir tablets is safe and effective in people 18 years of age and older with chickenpox.
- It is not known if valacyclovir tablets is safe and effective in children:
 - less than 12 years of age with cold sores
 - less than 2 years of age with chickenpox
 - less than 18 years of age with genital herpes or shingles

Do not take valacyclovir tablets if you are allergic to valacyclovir, acyclovir, or any of the ingredients in valacyclovir tablets.

See the end of this leaflet for a complete list of ingredients in valacyclovir tablets.

Before you take valacyclovir tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have had a bone marrow transplant or kidney transplant, or if you have advanced HIV-1 infection or acquired immune deficiency syndrome (AIDS).
- have kidney problems, including if you receive dialysis.
- are pregnant or plan to become pregnant. It is not known if valacyclovir tablets will harm your unborn baby. You and your healthcare provider will decide if you will take valacyclovir tablets if you are pregnant.
- are breastfeeding or plan to breastfeed. valacyclovir tablets may pass into your breastmilk. Talk with your healthcare provider about the best way to feed your child if you take valacyclovir tablets.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I take valacyclovir tablets?

- Take valacyclovir tablets exactly as your healthcare provider tells you to take it.
- Your dose of valacyclovir tablets and length of treatment will depend on the type of 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.
- Take valacyclovir tablets with or without food.
- Tell your healthcare provider if your child cannot swallow valacyclovir tablets. Your healthcare provider can prescribe valacyclovir tablets as an oral suspension for your child.
- If you are taking valacyclovir tablets to treat outbreaks of cold sores, chickenpox, shingles, or genital herpes, take valacyclovir tablets as soon as you have the first symptoms of infection such as tingling, itching, or burning, or when the sore appears.
- It is important for you to stay well hydrated during treatment with valacyclovir tablets. Be sure to drink plenty of fluids during this time.
- If you miss a dose of valacyclovir tablets, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose. Take the next dose at your regular time. Do not take 2 doses at the same time or take more valacyclovir tablets than prescribed.
- If you take too much valacyclovir tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of valacyclovir tablets?

Valacyclovir tablets can cause serious side effects including:

- **Thrombotic Thrombocytopenic Purpura (TTP) and Hemolytic Uremic Syndrome (HUS).** TTP and HUS have happened in people with weakened immune systems taking valacyclovir tablets and have led to death. TTP and HUS are disorders that can cause small blood clots to form throughout the body and decrease blood flow to body organs such as the brain, heart, and kidneys. Your healthcare provider will stop treatment with valacyclovir tablets if you have signs or symptoms of TTP and HUS.
- **kidney failure.**
- **nervous system problems.** Tell your healthcare provider right away if you get any of these signs or symptoms of nervous system problems during treatment with valacyclovir tablets:
 - o aggressive behavior
 - o unsteady movement
 - o shaky movements
 - o confusion
 - o speech problems
 - o hallucinations (seeing or hearing things that are really not there)
 - o seizures
 - o coma

Elderly people are more likely to get certain side effects. Talk to your healthcare provider if this is a concern for you.

The most common side effects of valacyclovir tablets in adults include:

- headache
- stomach (abdominal) pain
- nausea

The most common side effect of valacyclovir tablets in children less than 18 years of age is headache.

These are not all the possible side effects of valacyclovir tablets.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store valacyclovir tablets?

- Store valacyclovir tablets at room temperature, 20° to 25°C (68° to 77°F).
- Store valacyclovir suspension between 2° to 8°C (36° to 46°F) in a refrigerator. Throw away (discard) any remaining valacyclovir suspension after 28 days.
- Shake valacyclovir suspension bottle well before using.
- Keep valacyclovir tablets in a tightly closed container.

Keep valacyclovir tablets and all medicines out of the reach of children.

General information about the safe and effective use of valacyclovir tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. 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 that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about valacyclovir tablets that is written for health professionals.

What are the ingredients in valacyclovir tablets?

Active ingredient: valacyclovir hydrochloride

Inactive ingredients: anhydrous dibasic calcium phosphate, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #2, hypromellose, magnesium stearate, polyethylene glycol 400, polysorbate 80, povidone K90, and titanium dioxide.

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