

722 Patient labeling is provided as a tear-off leaflet at the end of this full prescribing
723 information.
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740 PHARMACIST-DETACH HERE AND GIVE INSTRUCTIONS TO PATIENT
741 -----

742 **PATIENT INFORMATION**

743 **VALTREX® (VAL-trex)**

744 **(valacyclovir hydrochloride) Caplets**
745

746 Read the Patient Information that comes with VALTREX before you start using it and each time
747 you get a refill. There may be new information. This information does not take the place of
748 talking to your healthcare provider about your medical condition or treatment. Ask your
749 healthcare provider or pharmacist if you have questions.
750

751 **What is VALTREX?**

752 VALTREX is a prescription antiviral medicine. VALTREX lowers the ability of herpes viruses
753 to multiply in your body.
754

755 VALTREX is used in adults:

- 756 • to treat cold sores (also called fever blisters or herpes labialis)
- 757 • to treat shingles (also called herpes zoster)
- 758 • to treat or control genital herpes outbreaks in adults with normal immune systems

- 759 • to control genital herpes outbreaks in adults infected with the human immunodeficiency virus
760 (HIV) with CD4+ cell count greater than 100 cells/mm³
761 • with safer sex practices to lower the chances of spreading genital herpes to others. Even with
762 safer sex practices, it is still possible to spread genital herpes.

763
764 VALTREX used daily with the following safer sex practices can lower the chances of passing
765 genital herpes to your partner.

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

769

770 VALTREX is used in children:

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

773

774 **VALTREX does not cure herpes infections** (cold sores, chickenpox, shingles, or genital
775 herpes).

776

777 The efficacy of VALTREX has not been studied in children who have not reached puberty.

778

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

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

783

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

787

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

793

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

797 VALTREX, taken every day as prescribed and used with the following **safer sex practices**, can
798 lower the chances of passing genital herpes to your partner.

799

800 • Do not have sexual contact with your partner when you have any symptom or outbreak of
801 genital herpes.

802 • Use a condom made of latex or polyurethane whenever you have sexual contact.

803

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

805

806 **Who should not take VALTREX?**

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

810

811 **Before taking VALTREX, tell your healthcare provider:**

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

813 • **if you have had a bone marrow transplant or kidney transplant, or if you have**
814 **advanced HIV disease or "AIDS"**. Patients with these conditions may have a higher chance
815 for getting a blood disorder called thrombotic thrombocytopenic purpura/hemolytic uremic
816 syndrome (TTP/HUS). TTP/HUS can result in death.

817 • **if you have kidney problems.** Patients with kidney problems may have a higher chance for
818 getting side effects or more kidney problems with VALTREX. Your healthcare provider may
819 give you a lower dose of VALTREX.

820 • **if you are 65 years of age or older.** Elderly patients have a higher chance of certain side
821 effects. Also, elderly patients are more likely to have kidney problems. Your healthcare
822 provider may give you a lower dose of VALTREX.

823 • **if you are pregnant or planning to become pregnant.** Talk with your healthcare provider
824 about the risks and benefits of taking prescription drugs (including VALTREX) during
825 pregnancy.

826 • **if you are breastfeeding.** VALTREX may pass into your milk and it may harm your baby.
827 Talk with your healthcare provider about the best way to feed your baby if you are taking
828 VALTREX.

829 • **about all the medicines you take,** including prescription and non-prescription medicines,
830 vitamins, and herbal supplements. VALTREX may affect other medicines, and other
831 medicines may affect VALTREX. It is a good idea to keep a complete list of all the
832 medicines you take. Show this list to your healthcare provider and pharmacist any time you
833 get a new medicine.

834

835 **How should I take VALTREX?**

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

- 839 • Do not stop VALTREX or change your treatment without talking to your healthcare
840 provider.
841 • VALTREX can be taken with or without food.
842 • If you are taking VALTREX to treat cold sores, chickenpox, shingles, or genital herpes, you
843 should start treatment as soon as possible after your symptoms start. VALTREX may not
844 help you if you start treatment too late.
845 • If you miss a dose of VALTREX, take it as soon as you remember and then take your next
846 dose at its regular time. However, if it is almost time for your next dose, do not take the
847 missed dose. Wait and take the next dose at the regular time.
848 • Do not take more than the prescribed number of VALTREX Caplets each day. Call your
849 healthcare provider right away if you take too much VALTREX.
850

851 **What are the possible side effects of VALTREX?**

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

860
861 Common side effects of VALTREX in adults include headache, nausea, stomach pain, vomiting,
862 and dizziness. Side effects in HIV-infected adults include headache, tiredness, and rash. These
863 side effects usually are mild and do not cause patients to stop taking VALTREX.
864

865 Other less common side effects in adults include painful periods in women, joint pain,
866 depression, low blood cell counts, and changes in tests that measure how well the liver and
867 kidneys work.
868

869 The most common side effect seen in children <18 years of age was headache.
870

871 **Talk to your healthcare provider if you develop any side effects that concern you.**
872

873 These are not all the side effects of VALTREX. For more information ask your healthcare
874 provider or pharmacist.
875

876 **How should I store VALTREX?**

- 877 • Store VALTREX Caplets at room temperature, 59° to 77°F (15° to 25°C).

- 878 • Store VALTREX suspension between 2° to 8°C (36° to 46°F) in a refrigerator. Discard after
879 28 days.
880 • Keep VALTREX in a tightly closed container.
881 • Do not keep medicine that is out of date or that you no longer need.
882 • Keep VALTREX and all medicines out of the reach of children.
883

884 **General information about VALTREX**

885 Medicines are sometimes prescribed for conditions that are not mentioned in patient information
886 leaflets. Do not use VALTREX for a condition for which it was not prescribed. Do not give
887 VALTREX to other people, even if they have the same symptoms you have. It may harm them.
888

889 This leaflet summarizes the most important information about VALTREX. If you would like
890 more information, talk with your healthcare provider. You can ask your healthcare provider or
891 pharmacist for information about VALTREX that is written for health professionals. More
892 information is available at www.VALTREX.com.
893

894 **What are the ingredients in VALTREX?**

895 **Active Ingredient:** valacyclovir hydrochloride

896 **Inactive Ingredients:** carnauba wax, colloidal silicon dioxide, crospovidone, FD&C Blue No. 2
897 Lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol,
898 polysorbate 80, povidone, and titanium dioxide.
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