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Source : U.S. National Library of Medicine

URL of this page: <https://medlineplus.gov/druginfo/meds/a600035.html>

Nevirapine

pronounced as (ne vye' ra peen)

IMPORTANT WARNING:

Nevirapine can cause severe, life-threatening liver damage, skin reactions, and allergic reactions. Tell your doctor if you have or have ever had liver disease, especially hepatitis B or C. Your doctor will probably tell you not to take nevirapine. Also tell your doctor if you have a rash or other skin condition before you start taking nevirapine. If you experience any of the following symptoms, stop taking nevirapine and call your doctor immediately: rash, especially if it is severe or comes along with any of the other symptoms on this list; excessive tiredness; lack of energy or general weakness; nausea; vomiting; loss of appetite; dark (tea colored) urine; pale stools; yellowing of the skin or eyes; pain in the upper right part of the stomach; fever; sore throat, chills, or other signs of infection; flu-like symptoms; muscle or joint aches; blisters; mouth sores; red or swollen eyes; hives; itching; swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs; hoarseness; or difficulty breathing or swallowing.

If your doctor tells you to stop taking nevirapine because you had a serious skin or liver reaction, you should never take nevirapine again.

Your doctor will start you on a low dose of nevirapine and increase your dose after 14 days. This will decrease the risk that you will develop a serious skin reaction. If you develop any type of rash or any of the symptoms listed above while you are taking a low dose of nevirapine, call your doctor right away. Do not increase your dose until your rash or symptoms have gone away.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain tests to check your body's response to nevirapine, especially during the first 18 weeks of your treatment.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with nevirapine and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also obtain the Medication Guide from the FDA website:

<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>

[<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>] .

Talk to your doctor about the risks of taking nevirapine. There is a greater risk that you will develop serious liver damage during your treatment if you are a woman and if you have a high CD4 count (large number of a certain type of infection fighting cell in your blood).

Why is this medication prescribed?

Nevirapine is used along with other medications to treat human immunodeficiency virus (HIV) infection in adults and children 15 days of age and older. Nevirapine should not be used to treat healthcare workers or other individuals exposed to HIV infection after contact with HIV-contaminated blood, tissues, or other body fluids. Nevirapine is in a class of medications called non-nucleoside reverse transcriptase inhibitors (NNRTIs). It works by decreasing the amount of HIV in the blood. Although nevirapine does not cure HIV, it may decrease your chance of developing acquired immunodeficiency syndrome (AIDS) and HIV-related illnesses such as serious infections or cancer. Taking these medications along with practicing safer sex and making other life-style changes may decrease the risk of transmitting (spreading) the HIV virus to other people.

How should this medicine be used?

Nevirapine comes as a tablet, an extended-release tablet, and a suspension (liquid) to take by mouth with or without food. The tablet and suspension are usually taken once a day for 2 weeks and then twice a day after the first 2 weeks. The extended-release tablet is usually taken once a day, following at least two weeks of treatment with regular nevirapine tablets or suspension. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take nevirapine exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow nevirapine with liquids such as water, milk, or soda.

Swallow the extended-release tablets whole; do not split, chew, or crush them.

Shake the liquid gently before each use to mix the medication evenly. Use an oral dosing cup or dosing syringe to measure your dose. It is best to use a syringe, especially if your dose is less than 5 mL (1 teaspoon). If you use a dosing cup, first drink all of the medication that you measured in the dosing cup. Then fill the dosing cup with water and drink the water to be sure that you get your full dose.

Nevirapine may control HIV but will not cure it. Continue to take nevirapine even if you feel well. Do not stop taking nevirapine or any of the other medications that you are taking to treat HIV or AIDS without talking to your doctor. Your doctor will probably tell you to stop taking your medications in a certain order. If you miss doses or stop taking nevirapine, your condition may become more difficult to treat.

If you do not take nevirapine for 7 days or longer, do not start taking it again without talking to your doctor. Your doctor will start you on a low dose of nevirapine, and increase your dose after 2 weeks.

Other uses for this medicine

Nevirapine is also sometimes used to prevent unborn babies whose mothers have HIV or AIDS from becoming infected with HIV during birth.

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking nevirapine,

- tell your doctor and pharmacist if you are allergic to nevirapine or any other medications.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, and nutritional supplements you are taking. Be sure to mention any of the following: anticoagulants ('blood thinners') such as warfarin (Coumadin); certain antifungals such as fluconazole (Diflucan), itraconazole (Sporanox), ketoconazole (Nizoral), and voriconazole (Vfend); birth control pills when you are taking them for reasons other than to prevent pregnancy; calcium channel blockers such as diltiazem (Cardizem, Dilacor, Tiazac), nifedipine (Adalat, Procardia), and verapamil (Calan, Covera, Isoptin, Verelan); clarithromycin (Biaxin); certain cancer chemotherapy medications such as cyclophosphamide (Cytoxan); cisapride (Propulsid); cyclosporine (Neoral, Sandimmune); ergot alkaloids such as ergotamine (Cafergot, Ercaf, others); fentanyl (Duragesic, Actiq); medications for irregular heartbeat such as amiodarone (Cordarone) and disopyramide (Norpace); medications for seizures such as carbamazepine (Tegretol), clonazepam (Klonopin), and ethosuximide (Zarontin); methadone (Dolophine), other medications for HIV or AIDS such as amprenavir (Agenerase), atazanavir (Reyataz), efavirenz (Sustiva), fosamprenavir (Lexiva), indinavir (Crixivan), lopinavir and ritonavir combination (Kaletra), nelfinavir (Viracept), and saquinavir (Fortovase, Invirase); prednisone (Deltasone); rifabutin (Mycobutin); rifampin (Rifadin, Rimactane); sirolimus (Rapamune); and tacrolimus (Prograf). Many other medications may interact with nevirapine, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list. Your doctor may need to change the doses of your medications or monitor you more carefully for side effects.
- tell your doctor and pharmacist what herbal products you are taking, especially St. John's wort.
- tell your doctor if you have or have ever had kidney disease, especially if you are being treated with dialysis (treatment to clean the blood outside the body when the kidneys are not working well).
- tell your doctor if you are pregnant or plan to become pregnant. If you become pregnant while taking nevirapine, call your doctor. You should not breastfeed if you are infected with HIV or are taking nevirapine.
- you should know that this medication may decrease fertility in women. Talk to your doctor about the risks of taking this medication if you have concerns about fertility.
- you should know that your body fat may increase or move to other areas of your body such as your waist, upper back, neck ("buffalo hump"), breasts, and around your stomach. You may notice a loss of body fat from your face, legs, and arms.
- you should know that while you are taking medications to treat HIV infection, your immune system may get stronger and begin to fight other infections that were already in your body or cause other conditions to occur. This may cause you to develop symptoms of those infections or conditions. If you have new or worsening symptoms during your treatment with nevirapine, be sure to tell your doctor.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Nevirapine may cause side effects. Tell your doctor if either of these symptoms is severe or does not go away:

- headache
- diarrhea
- stomach pain

Some side effects can be serious. If you experience any of the symptoms listed in the IMPORTANT WARNING section, call your doctor immediately.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed,

had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include the following:

- swelling of the hands, feet, ankles, or lower legs
- painful red bumps on the skin
- excessive tiredness
- fever
- headache
- difficulty falling asleep or staying asleep
- nausea
- vomiting
- rash
- dizziness

What other information should I know?

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

If you are taking the extended-release tablets, you may notice something that looks like a tablet in your stool. This is just the empty tablet shell, and this does not mean that you did not get your complete dose of medication.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Viramune[®]
- Viramune[®] XR

Last Revised - 02/15/2018

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National Library of Medicine 8600 Rockville Pike, Bethesda, MD 20894 U.S. Department of Health and Human Services

National Institutes of Health

Page last updated: 25 March 2022