

**MEDICATION GUIDE**  
**NEVIRAPINE (ne vir' a peen)**  
**EXTENDED-RELEASE TABLETS, USP**

**What is the most important information I should know about nevirapine extended-release tablets?**

Nevirapine extended-release tablets can cause severe liver and skin problems that may lead to death. These problems can happen at any time during treatment, but your risk is higher during the first 18 weeks of treatment.

**Nevirapine extended-release tablets can cause serious side effects, including:**

- **Severe liver problems.** Some people taking nevirapine extended-release tablets may develop severe liver problems, that can lead to liver failure and the need for a liver transplant, or death. If you have liver problems you may get a rash.
  - o Women have a higher risk of developing liver problems during treatment with nevirapine extended-release tablets than men.
  - o People who have abnormal liver test results before starting nevirapine extended-release tablets and people with hepatitis B or C also have a greater risk of getting liver problems.

**People who have higher CD4<sup>+</sup> cell counts when they begin nevirapine extended-release tablets have a higher risk of liver problems, especially:**

- o Women with CD4<sup>+</sup> counts higher than 250 cells/mm<sup>3</sup>. This group has the highest risk.
- o Men with CD4<sup>+</sup> counts higher than 400 cells/mm<sup>3</sup>.

**Stop taking nevirapine extended-release tablets and call your doctor right away if you have any of the following symptoms of liver problems with or without a skin rash:**

- dark (tea colored) urine or whites of eyes
- light-colored bowel movements (stools)
- feeling sick to your stomach (nausea)
- pain or tenderness on your right side below your ribs
- loss of appetite
- yellowing of your skin or your eyes
- fever

- **Severe skin reactions and rash.** Some skin reactions and rashes may be severe, life-threatening, and in some people, may lead to death. Most severe skin reactions and rashes happen in the first 6 weeks of treatment with nevirapine.

- o Women have a higher risk of developing a rash during treatment with nevirapine than men.

**Stop taking nevirapine and call your doctor right away if you get a rash with any of the following symptoms:**

- blisters
- red or inflamed eyes, like "pink eye" (conjunctivitis)
- swelling of your face
- feel unwell or like you have the flu
- muscle or joint aches
- mouth sores
- fever
- tiredness

- Your doctor should do blood tests often to check your liver function and check for severe skin reactions during the first 18 weeks of treatment with nevirapine extended-release tablets. You should continue to see your doctor and have your liver checked regularly during your treatment with nevirapine extended-release tablets. It is important for you to keep all of your doctor appointments.

- If your doctor tells you to stop treatment with nevirapine extended-release tablets because you have had any of the severe liver or skin symptoms listed above, you should never take nevirapine extended-release tablets again.

See "What are the possible side effects of nevirapine extended-release tablets?" for more information about side effects.

**What are nevirapine extended-release tablets?**

Nevirapine extended-release tablets are prescription HIV-1 medicines used with other HIV-1 medicines to treat HIV-1 (Human Immunodeficiency Virus 1) in adults and in children 15 days of age or older. HIV-1 is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

Nevirapine extended-release tablets are a prescription medicine used with other HIV-1 medicines to treat HIV-1 (Human Immunodeficiency Virus 1) in adults and in children 6 years of age or older based on the child's weight and height.

- If you are a woman with CD4<sup>+</sup> counts higher than 250 cells/mm<sup>3</sup> or a man with CD4<sup>+</sup> counts higher than 400 cells/mm<sup>3</sup>, you and your doctor will decide if starting nevirapine tablets is right for you.
- Nevirapine extended-release tablets are not recommended for use in children less than 6 years of age.

**Do not take nevirapine extended-release tablets:**

- if you have liver problems.
- as part of occupational and non-occupational post-exposure prophylaxis (PEP) regimens. Nevirapine extended-release tablets are only for people diagnosed with HIV-1. If you have not been diagnosed as HIV positive, then do not take nevirapine tablets.

**Before taking nevirapine tablets, tell your doctor about all your or your child's medical conditions, including if you or your child:**

- have or have had hepatitis (inflammation of your liver) or problems with your liver. See "What is the most important information I should know about nevirapine tablets?"
- receive dialysis
- have trouble swallowing pills
- are pregnant or plan to become pregnant. It is not known if nevirapine tablets will harm your unborn baby.

**Pregnancy Registry:** There is a pregnancy registry for women who take nevirapine tablets during pregnancy. The purpose of the registry is to collect information about the health of you and your baby. Talk to your doctor about how you can take part in this registry.

- are breastfeeding or plan to breastfeed. Nevirapine can pass into your breast milk and may harm your baby. You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby. Do not breastfeed during treatment with nevirapine. Talk to your doctor about the best way to feed your baby.

**Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Especially tell your doctor if you take St. John's wort.**

- Some medicines interact with nevirapine. Keep a list of your medicines to show your doctor or pharmacist.
- You can ask your doctor or pharmacist for a list of medicines that interact with nevirapine.
- **Do not start taking a new medicine without telling your doctor.** Your doctor can tell you if it is safe to take nevirapine extended-release tablets with other medicines.

**How should I take nevirapine extended-release tablets?**

- Take nevirapine extended-release tablets exactly as your doctor tells you to take it. Do not change

**your dose unless your doctor tells you to.**

- Nevirapine extended-release tablets are always taken in combination with other antiretroviral medicines.
- Nevirapine come in three different forms. Your doctor will prescribe the form of nevirapine that is right for you.
  - o Nevirapine tablets
  - o Nevirapine oral suspension
  - o Nevirapine extended-release tablets
- You should not take more than one form of nevirapine at the same time. Talk to your doctor if you have any questions.
- If your child is prescribed nevirapine, your child's doctor will tell you exactly how nevirapine should be taken.
- Nevirapine can be taken with or without food.
- Swallow nevirapine extended-release tablets whole. Do not chew, crush, or divide nevirapine extended-release tablets.
- Do not miss a dose of nevirapine. If you miss a dose of nevirapine, take the missed dose as soon as you remember. If it is almost time for your next dose, do not take the missed dose. You should take the next dose at your regular time. Do not take 2 doses at the same time.
- If you stop taking nevirapine for more than 7 days, ask your doctor how much to take before you start taking it again. You may need to begin taking the nevirapine starting dose again, which is taken 1 time each day for 14 days.

**Starting nevirapine tablets:**

1. Your doctor should start you with 1 dose each day to lower your chance of getting a serious rash. **It is important that you only take 1 dose of nevirapine each day for the first 14 days.**
  - **Call your doctor right away if you get a skin rash during the first 14 days of nevirapine treatment.**
  - **Do not increase your dose to 2 times a day if you have a rash.**
  - You should never take your starting dose for longer than 28 days. If after 28 days you are still receiving this starting dose because you have a rash, you and your doctor should talk about prescribing another HIV-1 medicine for you instead of nevirapine.

2. Day 15, you will take 1 nevirapine tablet 2 times a day. **Starting nevirapine extended-release tablets when this is the first time you are taking any form of nevirapine:**

1. Your doctor should start you with 1 dose of nevirapine tablets each day to lower your risk of getting a serious rash. **It is important that you only take 1 dose of nevirapine each day for the first 14 days.**
  - **Call your doctor right away if you get a skin rash during the first 14 days of nevirapine treatment.**
  - You should never take your starting dose for longer than 28 days. If after 28 days you are still receiving this starting dose because you have a rash, you and your doctor should talk about prescribing another HIV-1 medicine for you instead of nevirapine.
  - **Do not start nevirapine extended-release tablets if you have a rash.**

2. Day 15, take nevirapine extended-release tablets 1 time a day as prescribed by your doctor.

**Switching from nevirapine tablets or oral suspension to nevirapine extended-release tablets:**

- Take nevirapine extended-release tablets 1 time a day as prescribed by your doctor.
- You may sometimes pass a soft mass in your stools (bowel movement) that looks like your nevirapine extended-release tablets. This will not affect the way your medicine works.

**What are the possible side effects of nevirapine?**

**Nevirapine may cause serious side effects, including:**

See "**What is the most important information I should know about nevirapine?**"

- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your doctor right away if you start having new symptoms after starting your HIV-1 medicine.
- **Changes in body fat** can happen in people who take HIV-1 medicines. These changes may include increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the middle of your body (trunk). Loss of fat from your legs, arms, and face may also happen. The exact cause and long-term health effects of these conditions are not known.

**The most common side effect of nevirapine is rash.**

Nevirapine may cause decreased fertility in females. Talk to your doctor if you have concerns about fertility. These are not all the possible side effects of nevirapine. For more information, ask your doctor or pharmacist. 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 nevirapine ?**

- Store nevirapine extended-release tablets at room temperature between 68°F to 77°F (20°C to 25°C).

**Keep nevirapine extended-release tablets and all medicines out of the reach of children.**

**General information about the safe and effective use of nevirapine.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use nevirapine extended-release tablets for a condition for which it was not prescribed. Do not give nevirapine extended-release tablets to other people, even if they have the same condition you have. It may harm them. You can ask your pharmacist or doctor for information about nevirapine extended-release tablets that is written for health professionals.

**What are the ingredients in nevirapine?**

**Active ingredient:** nevirapine  
**Inactive ingredients: Nevirapine extended-release tablets :** Lactose monohydrate, hypromellose, ferric oxide, povidone and magnesium stearate.

For additional information you may also call Macleods Pharma USA, Inc. at 1-888-943-3210 or 1-855-926-3384.

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**This Medication Guide has been approved by the U.S. Food and Drug Administration**