





## MEDICATION GUIDE

### Nevirapine 50 mg Tablets for Oral Suspension

Read this Medication Guide before your child or you start taking nevirapine and each time your child or you get a refill because there may be new information. This information does not take the place of talking with your doctor. You and your doctor should discuss nevirapine when your child or you start taking medicine and at regular checkups. Your child or you should stay under a doctor's care while using nevirapine. Your child or you should consult with your doctor before making any changes to your medications, except in any of the special circumstances described below regarding rash or liver problems.

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

**Patients taking nevirapine may develop severe liver disease or skin reactions that can cause death.** The risk of these reactions is greatest during the first 18 weeks of treatment, but these reactions also can occur later.

#### **Liver Reactions**

**Any patient can experience liver problems while taking nevirapine. However, women and patients who have higher CD4 counts when they begin nevirapine treatment have a greater chance of developing liver damage. Women with CD4 counts higher than 250 cells/mm<sup>3</sup> are at the greatest risk of these events. If you are a woman with CD4 > 250 cells/mm<sup>3</sup> or a man with CD4 > 400 cells/mm<sup>3</sup> you should not begin taking nevirapine unless you and your doctor have decided that the benefit of doing so outweighs the risk. Liver problems are often accompanied by a rash.**

Patients starting nevirapine with abnormal liver tests and patients with hepatitis B or C have a greater chance of developing further increases in liver tests after starting nevirapine and throughout therapy.

**In rare cases liver problems have led to liver failure and can lead to a liver transplant or death. Therefore, if your child or you develop any of the following symptoms of liver problems stop taking nevirapine and call your doctor right away:**

- general ill feeling or “flu-like” symptoms
- dark urine (tea colored)
- tiredness
- pale stools (bowel movements)
- nausea (feeling sick to your stomach)
- pain, ache, or sensitivity to touch on right side below the ribs
- lack of appetite
- yellowing of skin or whites of eyes

Your doctor should check your child or you and do blood tests often to check your or your child's liver function during the first 18 weeks of therapy. Checks for liver problems should continue regularly during treatment with nevirapine.

#### **Skin Reactions**

Skin rash is the most common side effect of nevirapine. Most rashes occur in the first 6 weeks of treatment. In a small number of patients, **rash can be serious and result in death. Therefore, if you develop a rash with any of the following symptoms stop using nevirapine and call your doctor right away:**

- general ill feeling or “flu-like” symptoms
- blisters
- fever
- mouth sores
- muscle or joint aches
- swelling of face
- conjunctivitis (red or inflamed eyes, like “pink eye”)
- tiredness
- any of the symptoms of liver problems discussed above

**If your doctor tells your child or you to stop treatment with nevirapine because your child or you have experienced the serious liver or skin reactions described above, never take nevirapine again.**

These are not all the side effects of nevirapine. See the section “**What are the possible**

**side effects of nevirapine?”** for more information. Tell your doctor if your child or you have any side effects from nevirapine.

#### **What is nevirapine?**

Nevirapine is a medicine used to treat Human Immunodeficiency Virus (HIV), the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

Nevirapine is a type of anti-HIV medicine called a “non-nucleoside reverse transcriptase inhibitor” (NNRTI). It works by lowering the amount of HIV in the blood (“viral load”). Your child or you must take nevirapine with other anti-HIV medicines. When taken with other anti-HIV medicines, nevirapine can reduce viral load and increase the number of CD4 cells (“T cells”). CD4 cells are a type of immune helper cell in the blood. Nevirapine may not have these effects in every patient.

Nevirapine does not cure HIV or AIDS, and it is not known if it will help you or your child live longer with HIV. People taking nevirapine may still get infections common in people with HIV (opportunistic infections). Therefore, it is very important that you or your child stay under the care of a doctor.

#### **Who should not take nevirapine?**

- Do not take nevirapine if you or your child are allergic to nevirapine or any of its ingredients. The active ingredient is nevirapine. Your doctor or pharmacist can tell you or your child about the inactive ingredients.
- Do not restart nevirapine after you or your child recover from serious liver or skin reactions that happened when you or your child took nevirapine.
- Do not take nevirapine if you or your child have severe liver problems.
- Do not take nevirapine if you or your child take certain medicines. (See “**Can I or my child take other medicines with nevirapine?**” for a list of medicines.)
- Do not take nevirapine if you or your child are not infected with HIV.

#### **What should I or my child tell the doctor before taking nevirapine?**

Before starting nevirapine, tell the doctor about all of your and your child's medical conditions, including if:

- You or your child have problems with liver or have had hepatitis
- You or your child are undergoing dialysis
- You or your child have skin conditions, such as a rash
- You are pregnant, planning to become pregnant, or are breast feeding

#### **How should I or my child take nevirapine?**

- Take the exact amount of nevirapine as the doctor prescribes. See the first section “**What is the most important information I should know about nevirapine?**”
- The dose of nevirapine for children is based on their size. Children's dosing starts with once a day for 14 days and then twice a day after that.

The usual dosing is as follows.

Nevirapine Tablets for Oral Suspension	Tablet Strength: 50 mg	Number of Tablets by Weight Bands (administered QD x 14 days, then BID thereafter)						
		5-8 kgs	9-12 kgs	13-18 kgs	19-24 kgs	25-30 kgs	31-38 kgs	>38 kgs
Lead-in Period (first 14 days)		1 tablet Once Daily	1.5 tablets Once Daily	2 tablets Once Daily	2.5 tablets Once Daily	3 tablets Once Daily	3.5 tablets Once Daily	4 tablets Once Daily
After the first 14 days		1 tablet Twice Daily	1.5 tablets Twice Daily	2 tablets Twice Daily	2.5 tablets Twice Daily	3 tablets Twice Daily	3.5 tablets Twice Daily	4 tablets Twice Daily

Use the following procedure for taking these tablets.

1. Place the tablet(s) in a container and add one teaspoonful (5 mL) of water per tablet.

2. Swirl the container until tablet(s) breaks up into pieces small enough for the child to swallow.
3. Drink the mixture immediately.
4. Rinse the container with additional small amount of water and drink the contents to assure that the entire dosage is taken.

DO NOT CHEW NEVIRAPINE TABLET FOR ORAL SUSPENSION OR SWALLOW THE INTACT TABLET. DO NOT MIX NEVIRAPINE TABLET FOR ORAL SUSPENSION WITH ANY LIQUID OTHER THAN WATER.

- You may take nevirapine with or without food.
- Do not miss a dose of nevirapine, because this could make the virus harder to treat. If you or your child forget to take nevirapine, take the missed dose right away. If it is almost time for the next dose, do not take the missed dose. Instead, follow the regular dosing schedule by taking the next dose at its regular time.
- If you or your child stop taking nevirapine for more than 7 days, ask your doctor how much to take before you or your child start taking it again. You or your child may need to start with once-a-day dosing.
- If you suspect that you or your child have taken too much nevirapine, contact local poison control center or emergency room right away.

#### **Can I or my child take other medicines with nevirapine?**

- Nevirapine may change the effect of other medicines, and other medicines can change the effect of nevirapine. Tell your doctors and pharmacists about **all** medicines you or your child take, including non-prescription medicines, vitamins and herbal supplements.
- Do **not** take Nizoral® (ketoconazole) or Rifadin®/Rifamate®/Rifater® (rifampin) with nevirapine.
- Tell your doctor if you or your child take Biaxin® (clarithromycin), Diflucan® (fluconazole), methadone, or Mycobutin® (rifabutin). Nevirapine may not be right for you or your child, or you or your child may need careful monitoring.
- It is recommended that you or your child not take products containing St. John's wort, which can reduce the amount of nevirapine in the body.
- If you take birth control pills, you should not rely on them to prevent pregnancy. They may not work if you take nevirapine. Talk with your doctor about other types of birth control that you can use.

#### **What should I or my child avoid while taking nevirapine?**

Avoid doing things that can spread HIV infection, as nevirapine does not stop you or your child from passing HIV infection to others. Do not share needles, other injection equipment or personal items that can have blood or body fluids on them, like toothbrushes and razor blades. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

The Centers for Disease Control and Prevention advises mothers with HIV not to breast feed so they will not pass HIV to the infant through their milk. Ask your doctor about the best way to feed your infant.

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

Nevirapine can cause serious liver damage and skin reactions that can cause death. Any patient can experience such side effects, but some patients are more at risk than others. See **“What is the most important information I should know about nevirapine?”** at the beginning of this Medication Guide.

Other common side effects of nevirapine include nausea, fatigue, fever, headache, vomiting, diarrhea, abdominal pain, and myalgia. This list of side effects is not complete. Ask your doctor or pharmacist for more information.

Changes in body fat have also been seen in some patients taking antiretroviral therapy. The changes may include increased amount of fat in the upper back and neck (“buffalo

hump”), breast, and around the trunk. Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these conditions are not known at this time.

#### **How do I store nevirapine?**

Store nevirapine at room temperature, between 59° to 86°F (15° to 30°C).

Throw away nevirapine that is no longer needed or out-of-date.

#### **Keep nevirapine and all medicines out of the reach of children.**

#### **General information about nevirapine**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use nevirapine for a condition for which it was not prescribed. Do not give nevirapine to other people, even if they have the same condition you or your child have. It may harm them.

This Medication Guide summarizes the most important information about nevirapine. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about nevirapine that is written for health professionals.

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

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