

Each tablet contains:
Nevirapine, USP (anhydrous) 100 mg

Usual Dosage: See accompanying
prescribing information.

**Tablets must be swallowed whole and
must not be chewed, crushed, or divided.**

**Keep this and all medication out of
the reach of children.**

**Store at 20° to 25°C (68° to 77°F). [See
USP Controlled Room Temperature.]**

Manufactured for:

Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.

Made in India

 **Mylan**[®] | Mylan.com

RMXA6950H

NDC 0378-6950-93

Nevirapine
Extended-release

Tablets

100 mg

**PHARMACIST: Dispense the accompanying
Medication Guide to each patient.**

 **Mylan**[®]

Rx only

30 Tablets

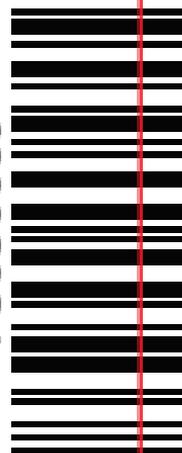


Dispense in a tight, light-resistant
container as defined in the USP
using a child-resistant closure.

Keep container tightly closed.

Code No.: MH/DRUGS/AD/089

75056689



VARNISH FREE AREA

**Prompt "LOT" & "EXP"
will be printed together
with Variable Data Coding.**

Each tablet contains:
Nevirapine, USP (anhydrous) 100 mg

Usual Dosage: See accompanying
prescribing information.

**Tablets must be swallowed whole and
must not be chewed, crushed, or divided.**

**Keep this and all medication out of
the reach of children.**

**Store at 20° to 25°C (68° to 77°F). [See
USP Controlled Room Temperature.]**

Manufactured for:
Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.

Made in India

 **Mylan**[®] | Mylan.com

RMXA6950MM

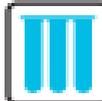
NDC 0378-6950-77

**Nevirapine
Extended-release**

Tablets

100 mg

**PHARMACIST: Dispense the accompanying
Medication Guide to each patient.**

 **Mylan**[®]

Rx only

90 Tablets

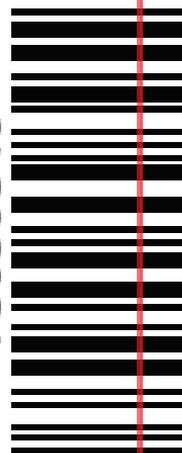


Dispense in a tight, light-resistant
container as defined in the USP
using a child-resistant closure.

Keep container tightly closed.

Code No.: MH/DRUGS/AD/089

75056348



VARNISH FREE AREA

**Prompt "LOT" & "EXP"
will be printed together
with Variable Data Coding.**

Each tablet contains:
Nevirapine, USP (anhydrous) 100 mg

Usual Dosage: See accompanying
prescribing information.

**Tablets must be swallowed whole and
must not be chewed, crushed, or divided.**

**Keep this and all medication out of the
reach of children.**

**Store at 20° to 25°C (68° to 77°F). [See
USP Controlled Room Temperature.]**

This container is not intended for dispensing
for household use.

Manufactured for:

Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.

Made in India

RMXA6950B

 **Mylan**[®] | Mylan.com

NDC 0378-6950-05

Nevirapine Extended-release

Tablets

100 mg

**PHARMACIST: Dispense the Medication
Guide provided separately to each patient.**

 **Mylan**[®]

Rx only

500 Tablets



Dispense in a tight, light-resistant
container as defined in the USP
using a child-resistant closure.

Keep container tightly closed.

Code No.: MH/DRUGS/AD/089

VARNISH FREE AREA

**Prompt "LOT" & "EXP"
will be printed together
with Variable Data Coding.**

75056730



MEDICATION GUIDE

NEVIRAPINE EXTENDED-RELEASE TABLETS

(ne vir’ a peen)

100 mg

Read this Medication Guide before you start taking nevirapine extended-release tablets and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or treatment.

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

Nevirapine can cause serious side effects. These include severe liver and skin problems that can cause death. These problems can happen at any time during treatment, but your risk is higher during the first 18 weeks of treatment.

1. Severe liver problems: Anyone who takes nevirapine may get severe liver problems. In some cases these liver problems can lead to liver failure and the need for a liver transplant, or death.

People who have a higher CD4+ cell count when they begin nevirapine treatment have a higher risk of liver problems, especially:

- Women with CD4+ counts higher than 250 cells/mm³. This group has the highest risk.
- Men with CD4+ counts higher than 400 cells/mm³.

If you are a woman with CD4+ counts higher than 250 cells/mm³ or a man with CD4+ counts higher than 400 cells/mm³, you and your doctor will decide whether starting nevirapine is right for you.

In general, women have a higher risk of liver problems compared to men.

People who have abnormal liver test results before starting nevirapine treatment and people with hepatitis B or C also have a greater risk of getting liver problems.

You may get a rash if you have liver problems.

Stop taking nevirapine and call your doctor right away if you have any of the following symptoms of liver problems:

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

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

2. Severe rash and skin reactions: Skin rash is the most common side effect of nevirapine. Most rashes happen in the first 6 weeks of taking nevirapine. **Rashes and skin reactions may be severe, life-threatening, and in some people, may lead to death. Stop using nevirapine and call your doctor right away if you get a rash with any of the following symptoms:**

- blisters
- swelling of your face
- mouth sores
- fever
- red or inflamed eyes, like “pink eye” (conjunctivitis)
- feel unwell or like you have the flu
- liver problems (see symptoms of liver problems above)
- tiredness
- muscle or joint aches

If your doctor tells you to stop treatment with nevirapine because you have had any of the serious liver or skin problems described above, you should never take nevirapine again.

See the section “**What are the possible side effects of nevirapine?**” for more information.

What is nevirapine?

• Nevirapine tablets and nevirapine oral solution are prescription HIV medicines used with other HIV medicines to treat HIV (Human Immunodeficiency Virus). HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

- Nevirapine extended-release tablets are a prescription medicine used with other HIV medicines to treat HIV (Human Immunodeficiency Virus) in adults and in children who are 6 years of age to less than 18 years of age.
- Nevirapine tablets and nevirapine extended-release tablets are a type of HIV medicine called a non-nucleoside reverse transcriptase inhibitor (NNRTI).

Nevirapine extended-release tablets are not for use in children less than 6 years of age.

When used with other HIV medicines, nevirapine may:

1. Reduce the amount of HIV in your blood (called “viral load”).
2. Help increase the number of CD4 (T) cells in your blood which help fight off other infections.

Reducing the amount of HIV and increasing the CD4 (T) cell count may improve your immune system. This may reduce your risk of death or infections that can happen when your immune system is weak (opportunistic infections).

Nevirapine does not cure HIV infection or AIDS.

Nevirapine does not cure HIV or AIDS and you may continue to experience illnesses associated with HIV-1 infection, including opportunistic infections. You should remain under the care of a doctor when using nevirapine.

You must stay on continuous HIV therapy to control HIV infection and decrease HIV-related illnesses.

Avoid doing things that can spread HIV-1 infection to others:

- **Do not share needles or other injection equipment.**
- **Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.**
- **Do not have any kind of sex without protection.** Always practice safe sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

Ask your doctor if you have any questions on how to prevent passing HIV to other people.

Who should not take nevirapine?

Tell your doctor if you have or have had liver problems. Your doctor may tell you not to take nevirapine if you have certain liver problems.

Nevirapine is only for people diagnosed with HIV. If you have not been diagnosed as HIV positive, then do not take nevirapine.

What should I tell my doctor before taking nevirapine?

Before you take nevirapine, tell your doctor if you:

- 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?**” and “**Who should not take nevirapine?**”
- receive dialysis
- have skin problems, such as a rash
- or your child has trouble swallowing pills
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if nevirapine will harm your unborn baby.

Pregnancy Registry: There is a pregnancy registry for women who take antiviral medicines 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 because of the risk of passing HIV 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 and pharmacist about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Nevirapine may affect the way other medicines work, and other medicines may affect how nevirapine works.

You should not take nevirapine if you also take:

- St. John’s wort. St. John’s wort can lower the amount of nevirapine in your body.
- efavirenz (Sustiva®, Atripla®) , etravirine (Intelence®), rilpivirine

(Edurant®, Complera®), or delavirdine (Rescriptor®).

- boceprevir (Victrelis®)
- telaprevir (Incivek®)
- atazanavir (Reyataz®)
- lopinavir and ritonavir (Kaletra®) once daily
- fosamprenavir calcium (Lexiva®) without ritonavir (Norvir®)
- itraconazole (Sporanox®)
- ketoconazole (Nizoral®)
- rifampin (Rifadin®, Rifamate®, Rifater®)
- birth control pills. Birth control pills taken by mouth (oral contraceptives) and other hormone types of birth control may not work to prevent pregnancy. Talk with your doctor about other types of birth control that you can use to prevent pregnancy during treatment with nevirapine.

Also tell your doctor if you take:

- clarithromycin (Biaxin®)
- fluconazole (Diflucan®)
- indinavir sulfate (Crixivan®)
- methadone
- nelfinavir mesylate (Viracept®)
- rifabutin (Mycobutin®)
- warfarin (Coumadin®, Jantoven®)
- saquinavir mesylate (Invirase®)
- amiodarone, disopyramide (Norpace®), lidocaine
- carbamazepine, clonazepam (Klonopin®), ethosuximide (Zarontin®)
- diltiazem, nifedipine, verapamil
- cyclophosphamide
- ergotamine
- cyclosporine, tacrolimus, sirolimus (Rapamune®)
- cisapride (Propulsid®)
- fentanyl

If you are not sure if you take a medicine above, ask your doctor or pharmacist.

Know the medicines you take. Keep a list of them to show your doctor or pharmacist when you get a new medicine.

How should I take nevirapine?

- Nevirapine is always taken in combination with other anti-HIV medications.
- Nevirapine comes 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

- Take nevirapine exactly as your doctor tells you to take it. Do not change your dose unless your doctor tells you to.
- You should never 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.
- Swallow nevirapine extended-release tablets whole. Do not chew, crush, or divide nevirapine extended-release tablets.
- You may take nevirapine with or without food.
- 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, just take the next dose at your regular time. Do not take two 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 one time each day for 14 days.

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 one dose of nevirapine tablets or oral suspension each day to lower your risk of getting a serious rash. **It is important that you only take one 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 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 one 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 one 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 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 if you start having new symptoms after starting your HIV medicine.
- **Changes in body fat** can happen in some people who take antiretroviral therapy. 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 can also happen. The cause and long-term health effects of these problems are not known at this time.

The most common side effect of nevirapine is rash.

Tell your doctor if you have any side effect that bothers you or that does not go away.

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 extended-release tablets?

- Store nevirapine extended-release tablets at room temperature between 20° to 25°C (68° to 77°F).
- Throw away nevirapine extended-release tablets that are no longer needed or out-of-date.

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

General information about nevirapine extended-release tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not take nevirapine 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. They may harm them.

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

For more information, call Mylan Pharmaceuticals Inc. at 1-877-446-3679 (1-877-4-INFO-RX).

What are the ingredients in nevirapine extended-release tablets?

Active ingredient: nevirapine, USP

Inactive ingredients: hypromellose, lactose monohydrate and sodium stearyl fumarate

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

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Manufactured for:
Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.

Manufactured in India by:
Mylan Laboratories Limited
Hyderabad — 500 034, India
Code No.: MH/DRUGS/AD/089

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MAY 2015
MXA:MG:NEV1:R1mh