

about other types of birth control that you can use to prevent pregnancy during treatment with nevirapine extended-release tablets.

Also tell your doctor if you take:

- clarithromycin (Biaxin®)
- flucanazole (Diflucan®)
- indinavir sulfate (Crixivan®)
- methadone
- nefazavir mesylate (Vireacep®)
- ribavirin (Myobutin®)
- warfarin (Coumadin®, Jantoven®)
- sacquinavir mesylate (Invirase®)
- cyclosporine
- zalcitabine, zalcitrimis, zalcitrimis (Rapamune®)
- cisapride (Propulsid®)
- fenofenyl

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 extended-release tablets?

- Nevirapine is always taken in combination with other anti-HIV medications.
- 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.
- You should never take more than one form of nevirapine at the same time. Talk to your doctor if you have any questions.
- Swallow nevirapine extended-release tablets whole. Do not chew, crush, or divide nevirapine extended-release tablets.
- You may take nevirapine extended-release tablets with or without food.

- Do not miss a dose of nevirapine extended-release tablets. If you miss a dose of nevirapine extended-release tablets, 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 extended-release tablets 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.

Pediatric use information is approved for Boehringer Ingelheim Pharmaceuticals, Inc.'s Viramune XR® (nevirapine) extended-release tablets. However, due to Boehringer Ingelheim Pharmaceuticals, Inc.'s marketing exclusivity rights, this drug product is not labeled with that information.

Starting nevirapine extended-release tablets when this is the first time you are taking any form of nevirapine:

- Your doctor should start you with 1 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 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 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 extended-release tablets?”**

- 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 at 25°C (77°F); excursions permitted to 15°C–30°C (59°F–86°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 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.

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, go to www.cipla.com or call Cipla Limited at 1-866-604-3268.

What are the ingredients in nevirapine extended-release tablets?

Active ingredient: nevirapine

Inactive ingredients:

Nevirapine Extended-Release Tablets: lactose monohydrate, hypromellose, iron oxide (yellow) and magnesium stearate

Pediatric use information is approved for Boehringer Ingelheim Pharmaceuticals, Inc.'s VIRAMUNE XR® (nevirapine extended-release) tablets. However, due to Boehringer Ingelheim Pharmaceuticals, Inc.'s marketing exclusivity rights, this drug product is not labeled with that information.

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Revised: 4/2015

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

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Manufactured by:

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Verna, Goa, India

Manufactured for:

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Suite S, Dadeland Blvd.,

Salt 1500 Miami, Florida 33156

← Penetration

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8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Registry B

There are no adequate and well-controlled trials of nevirapine in pregnant women. The Antiretroviral Pregnancy Registry, which has been surveying pregnancy outcomes since January 1988, has not found an increased risk of birth defects following first trimester exposures to nevirapine. The prevalence of birth defects after any trimester exposure to nevirapine is comparable to the prevalence observed in the general population.

Severe hepatic events, including fatalities, have been reported in pregnant women receiving chronic nevirapine therapy as part of combination treatment of HIV-1 infection. Regardless of pregnancy status, women with CD4+ cell counts greater than 250 cells/mm³ should not initiate nevirapine unless the benefit outweighs the risk. It is unclear if pregnancy augments the risk observed in non-pregnant women (see [Dosed Women](#)).

Nevirapine extended-release tablets should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

To monitor maternal-fetal outcomes of pregnant women exposed to immediate-release nevirapine and nevirapine extended-release, an Antiretroviral Pregnancy Registry has been established. Physicians are encouraged to register patients by calling (800) 258-9025.

Animal Data
No discernible teratogenicity was detected in reproductive studies performed in pregnant rats and rabbits. The maternal and developmental no-observable-effect level dosage produced systemic exposure approximately equivalent to or approximately 50% higher in rats and rabbits, respectively. These data are consistent with the recommended daily human dose (based on AUC). In rats, decreased fetal body weights were observed due to administration of a maternally toxic dose (exposures approximately 50% higher than that seen at the recommended human clinical dose).

8.3 Nursing Mothers

Guidelines for Disease Control and Prevention recommend that HIV-1 infected mothers not breastfeed their infants to avoid the risk of transmission of HIV-1. Nevirapine is excreted in breast milk. Because of both the potential for HIV-1 transmission and the potential for serious adverse reactions in nursing infants, mothers should be instructed not to breastfeed if they are receiving nevirapine extended-release tablets.

8.4 Pediatric Use

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8.5 Geriatric Use

Clinical studies of nevirapine extended-release did not include sufficient numbers of subjects aged 65 or older to determine whether older patients respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, reflecting the greater degree of sensitivity that may occur with advanced age, and of concomitant disease or other drug therapy.

8.6 Renal Impairment

In subjects with renal impairment (mild, moderate or severe), there were no significant changes in the pharmacokinetics of nevirapine. Nevirapine is extensively metabolized by the liver. Nevirapine metabolites are extensively eliminated by the kidney. Nevirapine metabolites may be excreted in breast milk. In subjects with renal impairment, the clinical significance of this accumulation is not known. No adjustment in nevirapine dosing is required in patients with CrCl greater than or equal to 30 mL per min. The pharmacokinetics of nevirapine has not been evaluated in patients with CrCl less than 30 mL per min. In patients with end-stage renal disease, an additional dose of immediate-release nevirapine (200 mg) following each dialysis treatment is indicated [see [Dosage and Administration \(2.2\)](#) and [Clinical Pharmacology \(12.2\)](#)]. Nevirapine extended-release has not been studied in patients with renal dysfunction.

8.7 Hepatic Impairment

Because nevirapine levels and nevirapine accumulation may be observed in patients with serious liver disease, do not administer nevirapine to patients with moderate or severe (Child-Pugh Class B or C, respectively) hepatic impairment (see [Contraindications \(4\)](#), [Warnings and Precautions \(5.1\)](#), and [Use in Specific Populations \(8.7\)](#)). Nevirapine extended-release has not been studied in patients with hepatic impairment.

In the multinational 2NN trial of immediate-release nevirapine, a population pharmacokinetic analysis of 1677 subjects was performed including 201 females. Female subjects showed a 13.8% lower clearance of nevirapine than did men. Since neither body weight nor Body Mass Index (BMI) had an influence on the clearance of nevirapine, the effect of gender cannot solely be explained by body size.

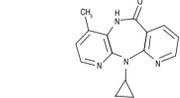
The effects of gender on the pharmacokinetics of nevirapine extended-release were investigated in Trial 1100-1486. Female subjects tend to have higher (approximately 20-30%) trough concentrations in both nevirapine extended-release and immediate-release nevirapine compared to males.

8.8 Overdosage

There is no known antidote for nevirapine overdose. Cases of immediate-release nevirapine overdose in doses ranging from 800 to 1800 mg per day for up to 15 days have been reported. Patients have experienced effects including dizziness, erythema nodosum, fatigue, fever, headache, insomnia, nausea, pulmonary edema, rash, vertigo, vomiting and weight decrease. All events subsided following discontinuation of immediate-release nevirapine.

11 DESCRIPTION

Nevirapine is a non-nucleoside reverse transcriptase inhibitor (NRTI) with activity against HIV-1 infection. Nevirapine is a member of the bicyclopiperidine 5,11-dihydro-4-methyl-6H-dipyrido [3,2-b:3',2'-a][1,4] diazepin-6-one. Nevirapine is a white to off-white crystalline powder with the molecular weight of 266.30 and the molecular formula C₁₄H₁₄N₄O. Nevirapine has the following structural formula:



Nevirapine extended-release tablets are oral administration. Each tablet contains 400 mg of nevirapine and the inactive ingredients lactose monohydrate, hypromellose, ferric oxide (yellow), and magnesium stearate.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Nevirapine is an antiviral drug [see [Microbiology \(12.4\)](#)].

12.2 Pharmacokinetics

Single-Dose Pharmacokinetics
The single-dose pharmacokinetics of nevirapine extended-release was studied in 17 healthy volunteers. Nevirapine was absorbed with a median *t*_{1/2} of approximately 24 hrs. The mean C₀₋₂ and AUC₀₋₂₄ of nevirapine were 2065 ng per mL and 161,000 ng·hr/mL, respectively. The bioavailability of 400 mg of nevirapine extended-release, relative to 400 mg of immediate-release nevirapine, was approximately 55%.

Multiple-Dose Pharmacokinetics
The multiple-dose pharmacokinetics of nevirapine extended-release was studied in 24 HIV-1 infected subjects who switched from chronic nevirapine IR to nevirapine extended-release. The mean nevirapine AUC₀₋₂₄ and C₀₋₂ after 19 days of nevirapine extended-release dosing under fasted conditions were 82,000 ng·hr/mL and 2503 ng per mL, respectively. When nevirapine extended-release was administered under fed conditions, the mean nevirapine AUC₀₋₂₄ and C₀₋₂ were 96,700 ng·hr/mL and 3350 ng per mL, respectively. The bioavailability of 400 mg of nevirapine extended-release, relative to 400 mg of immediate-release nevirapine, under fasted and fed conditions, was 80% and 84%, respectively. The difference in the bioavailability of nevirapine when nevirapine extended-release is dosed under fasted or fed conditions, is not considered clinically relevant. Nevirapine extended-release can be taken with or without food.

In Single-dose, parallel-group bioavailability trial (1100-1517) in adults, the nevirapine extended-release 100 mg tablet exhibited extended-release characteristics of prolonged absorption and lower maximal concentration, as compared to the immediate-release nevirapine 200 mg tablet.

Distribution
Nevirapine is highly lipophilic and is essentially nonionized at physiologic pH. Following intravenous administration to healthy adults, the apparent volume of distribution (V_{dss}) of nevirapine was 1.21 ± 0.08 L/kg, suggesting that nevirapine is widely distributed in humans. Nevirapine readily crosses the placenta and is also found in breast milk [see [Use in Specific Populations \(8.3\)](#)]. Nevirapine is about 60% bound to plasma proteins in the plasma concentration range of 1-10 mg per mL. Nevirapine concentrations in human cerebrospinal fluid (n=6) were 45% (±5%) of the concentrations in plasma; this ratio is approximately equal to the fraction not bound to plasma protein.

Metabolism/Excretion

In *in vivo* studies in humans and *in vitro* studies with human liver microsomes have shown that nevirapine is extensively biotransformed via cytochrome P450 (oxidative) metabolism to several hydroxylated metabolites. *In vitro* studies with human liver microsomes suggest that oxidative metabolism of nevirapine is mediated primarily by cytochrome P450 (CYP) isozymes from the CYP2A and CYP2B6 families, although other isozymes may have a secondary role. In a mass balance/increased trial in eight healthy male volunteers dosed to steady state with immediate-release nevirapine 200 mg given twice daily followed by a single 50 mg oral dose of ¹⁴C-nevirapine, approximately 81.4 ± 10.2% of the radioactivity was recovered, with urine (81.3 ± 11.1%), representing the primary route of excretion compared to feces (10.1 ± 1.5%). Greater than 90% of the radioactivity in urine was made up of glucuronide conjugates of hydroxylated metabolites. Thus, cytochrome P450 metabolism, glucuronide conjugation, and urinary excretion of glucuronidated metabolites represent the primary route of nevirapine biotransformation and elimination in humans. (Only a small fraction (less than 5%) of the radioactivity in urine (representing less than 3% of the total dose) was made up of parent compound; therefore, renal excretion plays a minor role in elimination of the parent compound.)

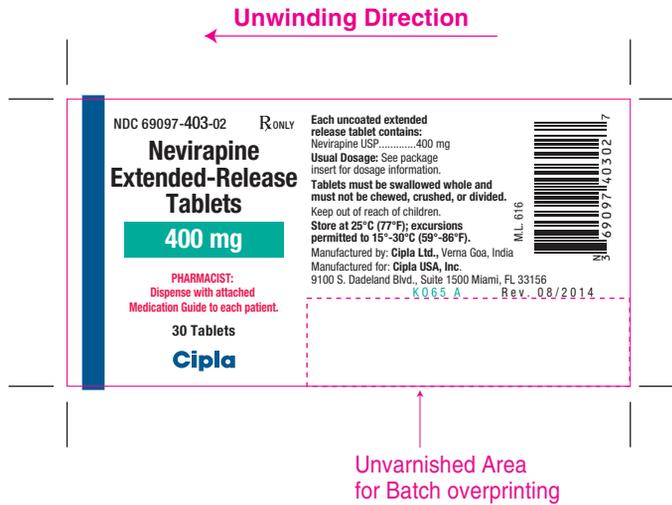
Nevirapine is an inducer of hepatic cytochrome P450 (CYP) metabolic enzymes 3A and 2B6. Nevirapine induces CYP3A and CYP2B6 by approximately 20-25%, as indicated by erythromycin breath test results and urine metabolites. Autoinduction of CYP3A and CYP2B6 mediated metabolism leads to an approximately 1.5- to 2-fold increase in the apparent oral clearance of nevirapine as treatment continues from a single dose to two-to-four weeks of dosing with 200

400 mg per day of immediate-release nevirapine. Autoinduction also results in a corresponding decrease in the terminal phase half-life of nevirapine in plasma, from approximately 45 hours (single dose) to approximately 25-30 hours following multiple dosing with 200-400 mg per day.

Specific Populations

Gender
Nevirapine AUC₀₋₂₄ and C₀₋₂ were similar in males and females. Female subjects showed a 13.8% lower clearance of nevirapine than did men. Since neither body weight nor BMI had an influence on the clearance of nevirapine, the effect of gender cannot solely be explained by body size.

Subjects with renal impairment (mild, moderate or severe), there were no significant changes in the pharmacokinetics of nevirapine. However, subjects requiring dialysis exhibited a 44% reduction in nevirapine AUC₀₋₂₄ and C₀₋₂ after 19 days of nevirapine extended-release dosing. In subjects with renal impairment (mild, moderate or severe), there were no significant changes in the pharmacokinetics of nevirapine. However, subjects requiring dialysis exhibited a 44% reduction in nevirapine AUC₀₋₂₄ and C₀₋₂ after 19 days of nevirapine extended-release dosing. In subjects with renal impairment (mild, moderate or severe), there were no significant changes in the pharmacokinetics of nevirapine. However, subjects requiring dialysis exhibited a 44% reduction in nevirapine AUC₀₋₂₄ and C₀₋₂ after 19 days of nevirapine extended-release dosing. In subjects with renal impairment (mild, moderate or severe), there were no significant changes in the pharmacokinetics of nevirapine. 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Actual Size : 75 x 38 mm

(b) (4)

Unwinding Direction



NDC 69097-403-11

R_X ONLY

Nevirapine Extended-Release Tablets

400 mg

PHARMACIST:
Dispense with attached
Medication Guide to each patient.

480 Tablets

Cipla

**Each uncoated extended
release tablet contains:**
Nevirapine USP.....400 mg

Usual Dosage: See package
insert for dosage information.

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

Keep out of reach of children.

**Store at 25°C (77°F); excursions
permitted to 15°-30°C (59°-86°F).**

Manufactured by: **Cipla Ltd.**, Verna Goa, India

Manufactured for: **Cipla USA, Inc.**
9100 S. Dadeland Blvd., Suite 1500 Miami, FL 33156

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M.L. 616



Unvarnished Area
for Batch overprinting

Actual Size : 120 x 65 mm

(b) (4)