nevirapine (nev-are-pen)

Virena, Virena-3R

Therapeutic: antiretroviral

Pharmacologic: non-nucleoside reverse transcriptase inhibitor

Pregnancy Category: B

Indications

Management of HIV infection in combination with a nucleoside analogue.

Action

Steady-state enzyme reverse transcriptase, which results in disruption of DNA synthesis.

Therapeutic Effects: Slowed progression of HIV infection and decreased occurrence of sequelae.

Pharmacokinetics

Absorption: -98% absorbed after oral administration.

Distribution: Grossly plasma and enters breast milk; GIR levels are 4% of those in plasma.

Metabolism and Excretion: Mostly metabolized by the liver (CYP3A4 enzyme system); minor amounts excreted unchanged in urine.

Half-life: 25–30 hr (during multiple dosing).

Pharmacodynamics

Time/ACTION PROFILE (blood levels)

- Onset: 2 hr
- Peak: 4 hr
- Duration: 15 days (immediate-release nevirapine) (safety not established).
- Crosses placenta and enters breast milk; CSF levels are 45% of those in plasma.

Indications

Therapeutic:

- Management of HIV infection in combination with a nucleoside analogue.
- Prevention of maternal infection in HIV-positive pregnant women (s=40 mg q24 hr for at least 28 days before delivery, then 40 mg q12 hr for 2 wks after delivery)
- Use as part of occupational and non-occupational post-exposure prophylaxis regimen.

Contraindications/Precautions

Contraindicated in: Hypersensitivity; Concurrent ketoconazole, rifampin, or St. John’s wort.

Use Cautiously in:

- Women with CD4 cell counts < 250 cells/mm3 (risk of liver toxicity)
- Use Cautionally in: Women (7% risk of liver toxicity), Hepatic or renal impairment, Concurrent clarithromycin, disulfiram, mefloquine, or rifabutin (careful monitoring required; alternative therapy should be considered);

- Children 0–6 yr (extended-release nevirapine) and <15 days (immediate-release nevirapine) (safety not established).

Adverse Reactions/Effects

Reflux, nausea, vomiting, abdominal pain, diarrhea, headache, respiratory symptoms, diarrhea, fever, rash, Stevens-Johnson syndrome, ENS-JOHNSON SYNDROME, fever, PNEUMONITIS, PROGRESS TO TOXIC EPIDERMAL NECROLYSIS (MAY CAUSE LIFE-THREATENING PROGRESS TO TOXIC EPIDERMAL NECROLYSIS, fever, Stevens-Johnson syndrome, ENS-JOHNSON SYNDROME, PROGRESS TO TOXIC EPIDERMAL NECROLYSIS)

- CNS: Headache
- Derm: Rash
- Gastro: Nausea, abdominal pain, diarrhea
- Hemat: Granulocytopenia (increased in liver enzymes, thrombocytopenia)
- Liver: Hepatitis, jaundice, elevated liver enzymes
- Misc: Flushing, pruritus, peripheral neuropathy
- Respiratory: wheezing, labored breathing

Interactions

Drug-Generic:

- Nevirapine induces the hepatic CYP3A4 enzyme system and can affect the behavior of drugs metabolized by this system. Significant: ketoconazole levels (concurrent use contraindicated). Use cautions methadone withdrawal within 2 weeks of starting therapy in patients physically dependent on methadone. May ↓ levels and effectiveness hormonal contraceptives (concurrent use of hormonal contraceptives should be avoided): Rifampin (consider other agents). Also may ↓ levels and effectiveness of the following: ENS-JOHNSON SYNDROME, fever, PNEUMONITIS, PROGRESS TO TOXIC EPIDERMAL NECROLYSIS (MAY CAUSE LIFE-THREATENING PROGRESS TO TOXIC EPIDERMAL NECROLYSIS, fever, Stevens-Johnson syndrome, ENS-JOHNSON SYNDROME, PROGRESS TO TOXIC EPIDERMAL NECROLYSIS)

- Cross-Resistance:

- Viral:

- Lopinavir/ritonavir:

- Abacavir
- Darunavir/ritonavir
- Efavirenz
- Indinavir
- Lopinavir/ritonavir
- Nelfinavir
- Ritonavir
- Saquinavir
- Tipranavir/ritonavir

- Drug-Drug:

- Nevirapine induces the hepatic CYP3A4 enzyme system and can affect the behavior of drugs metabolized by this system. Significant: 

- Ketoconazole levels (concurrent use contraindicated).
- Rifampin (consider other agents).

- Drug-Natural Products:

- St. John’s wort

Dosage

PO (Adults): Nevirapine immediate-release (IR)— 200 mg daily for the first 2 wks, then 200 mg twice daily (in combination with a nucleoside analogue antiretroviral). Ex-

PO (Adults): Nevirapine extended-release (ER)—200 mg daily for the first 2 wks, then 300 mg twice daily (in combination with a nucleoside analogue antiretroviral).

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Ex-
tended-release (ER) (for patients not currently taking IR nevirapine)—200 mg of IR nevirapine for the first 2 wk (to reduce risk of rash), then 400 mg of ER nevirapine once daily.

PO (Children 6–<18 yr and BSA ≥1.7 m²): IR—150 mg/m² of IR nevirapine daily (max = 200 mg/day) for the first 2 wk (to reduce risk of rash), then 400 mg of ER nevirapine once daily.

PO (Children 6–<18 yr and BSA = 0.84–1.16 m²): ER—150 mg/m² of IR nevirapine daily (max = 200 mg/day) for the first 2 wk (to reduce risk of rash), then 300 mg of ER nevirapine once daily.

PO (Children 6–<18 yr and BSA = 0.58–0.83 m²): ER—150 mg/m² of IR nevirapine daily (max = 200 mg/day) for the first 2 wk (to reduce risk of rash), then 200 mg of ER nevirapine once daily.

Renal Impairment
PO (Adults and Children): Dialysis—Give additional 200 mg of IR nevirapine after each dialysis session.

NURSING IMPLICATIONS
Assessment
● Assess for change in severity of HIV symptoms and for symptoms of opportunistic infections throughout therapy.
● Assess for rash (mild to moderate rash—erythema or maculopapular rash; urticaria, pruritic raised rash with welts; constitutional symptoms—fever, blistering, oral erosive lesions, conjunctivitis, facial edema, myalgia, arthralgia), especially during 1st 6 wk of therapy. If rash is severe (extensive erythematous or maculopapular rash with moist desquamation or angioedema) or accompanied by systemic symptoms (serum sickness-like reaction, Stevens-Johnson syndrome, toxic epidermal necrolysis), therapy must be discontinued immediately.

Lab Test Considerations: Monitor viral load and CD4 cell count regularly during therapy.

Monitor for liver function at baseline and frequently during the first 18 wk for toxicity, especially during first 6 wk of therapy. May be asymptomatic with AST and ALT without clinical signs or symptoms, or symptomatic with liver enzymes and at least one symptom (rash, flu-like symptoms, fever). May progress to liver failure and death. If signs of liver toxicity occur, permanently discontinue nevirapine.

Assess patient for hepatitis B and C. Patients with HBV and/or HCV are at risk for liver failure.

Potential Nursing Diagnoses
Risk for infection (Indications)
Noncompliance (Patient/Family Teaching)

Implementation
● Do not confuse nevirapine (Viramune) with nelfinavir (Viracept).

PO:
May be administered with or without food. Swallow extended-release tablets whole; do not crush, break, or chew.

Shake oral solution prior to administration. Use an oral dosing syringe for amounts ≥5 mL. Rinse syringe or cup and readminister to ensure patient receives full dose.

If therapy is interrupted for more than 7 days, restart therapy at 200 mg daily for 1–3 days, then increase dose to 200 mg twice daily.

Patient/Family Teaching
● Emphasize the importance of taking nevirapine as directed, at evenly spaced times throughout day. Instruct patient to read the Medication Guide prior to initiating therapy and with each Rx refill. Do not take more than prescribed amount and do not stop taking without consulting health care professional. Take missed doses as soon as remembered; do not double doses.

● Instruct patient to notify health care professional before taking any other medications, vitamins, or herbal products not being taken and to consult with health care professional before taking other medications.

● Inform patient that nevirapine does not cure AIDS or prevent associated opportunistic infections. Nevirapine does not reduce the risk of transmission of HIV to others through sexual contact or blood contamination. Caution patient to use a

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nevirapine

condone and avoid sharing needles or donating blood to prevent spreading the AIDS virus to others. Advise patients that the long-term effects of nevirapine are unknown at this time.

- Instruct patient to notify health care professional immediately if signs and symptoms of hepatitis (flu-like symptoms, tiredness, nausea, lack of appetite, yellow skin or eyes, dark urine, pale stools, pain or sensitivity to touch on right side below ribs), skin reactions with symptoms (flu-like symptoms, fever, muscle aches, conjunctivitis, blisters, mouth sores, swelling of face, tiredness), or signs of immune reconstitution syndrome (signs and symptoms of an infection) occur. Nevirapine should be discontinued immediately.

- Advise patients taking oral contraceptives to use a nonhormonal method of birth control during nevirapine therapy.

- Emphasize the importance of regular follow-up exams and blood counts to determine progress and monitor for side effects.

**Evaluation/Desired Outcomes**

- Delayed progression of AIDS and decreased opportunistic infections in patients with HIV.
- Decrease in viral load and increase in CD4 cell counts.

*Why was this drug prescribed for your patient?*

- Canadian drug name
- Genetic Implication
- Underlines indicate life-threatening.
- Underlines indicate most frequent.
- Strikethrough = Discontinued.