

Delavirdine (Rescriptor)

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What is Rescriptor?

- Rescriptor is an anti-HIV medication. It is in a category of HIV medicines called non-nucleoside reverse transcriptase inhibitors (NNRTIs). Rescriptor prevents HIV from entering the nucleus of healthy T-cells. This prevents the cells from producing new HIV and decreases the amount of virus in the body.
- Rescriptor, manufactured by Pfizer, was approved by the U.S. Food and Drug Administration for the treatment of HIV in 1997.
- Rescriptor must be used in combination with other drugs to treat HIV. It is usually combined with two nucleoside analogues.

What is known about Rescriptor?

- Rescriptor is available in 100mg tablets and 200mg capsules. The total daily dose is 400mg three times a day—either 4 tablets or 2 capsules in the morning, afternoon, and evening. The capsules are swallowed whole with a glass of water, juice, soda, or milk. The tablets can be dissolved in water or another liquid so that they are easier to swallow.

- You may take Rescriptor either with or without food.
- You should not take Rescriptor within an hour of taking an antacid medicine (e.g., Tums, Mylanta). This is because Rescriptor needs acid in the stomach in order to be absorbed properly.
- Some people have a medical condition called achlorhydria. This is a minor problem resulting in low amounts of acid in the stomach. HIV-positive people who have achlorhydria should take Rescriptor with a liquid that contains some acid, such as orange or cranberry juice.
- Rescriptor is not approved for use in HIV-positive children.
- For HIV-positive adults beginning anti-HIV drug therapy for the first time, Rescriptor is not listed as a recommended NNRTI option by the United States Department of Health and Human Services in its treatment guidelines. The NNRTI Sustiva® (efavirenz) is listed as the “preferred” option and the NNRTI Viramune® (nevirapine) is listed as an “alternative” option.

- If your viral load becomes detectable while taking a drug regimen that contains Rescriptor, your doctor can order a drug-resistance test to see which drugs your virus are becoming less sensitive to.
- All of the currently available NNRTIs are affected by cross-resistance. This means that, if you've tried and failed a drug regimen in the past that contained either Sustiva® (efavirenz) or Viramune® (nevirapine), your virus might be resistant to Rescriptor. Similarly, if you take an anti-HIV drug regimen that contains Rescriptor and your virus becomes resistant to the drug, your virus will most likely be resistant to the other NNRTIs. This is why it is very important to use drug-resistance testing to determine which drugs your virus is no longer responding to if you experience a rebound in your viral load while taking an anti-HIV drug regimen. Fortunately, new NNRTIs that are active against HIV strains resistant to current NNRTIs are being developed.

What about drug interactions?

- Rescriptor is broken down (metabolized) by the liver, like many medications used to treat HIV and AIDS. This means that Rescriptor can interact with other medications. Rescriptor can lower or raise the levels of other medications in the body. Similarly, other medications can lower or raise the levels of Rescriptor in the body. While many interactions are not a problem, some can cause your medications to be less effective or increase the risk of side effects.
- Tell your doctors and pharmacists about all medicines you take. This includes those you buy over-the-counter and herbal or natural remedies, such as St. John's Wort. Bring all your medicines when you see a doctor, or make a list of their names, how much you take, and how often you take them. Your doctor can then tell you if you need to change the dosages of any of your medications.

- The following medications should not be taken while you are being treated with Rescriptor:
 - Antibiotics:** Priftin® (rifapentine), Mycobutin (rifabutin), Rifadin® (rifampin)
 - Antihistamines:** Hismanal® (astemizole)
 - Acid reflux/heartburn medications:** Propulsid® (cisapride), Tagamet® (cimetidine), Pepcid® (famotidine), Zantac® (ranitidine), Prevacid® (lansoprazole), Nexium® (esomeprazole), Prilosec® (omeprazole), Protonix® (pantoprazole), and other H2 antagonists and proton-pump inhibitors.
 - Sedatives:** Versed® (midazolam) and Halcion® (triazolam)
 - Antimigraine medications:** Wigraine® and Cafergot® (ergot medications)
 - Cholesterol-lowering medications (statins):** Zocor® (simvastatin) and Mevacor® (lovastatin).
- Nucleoside reverse transcriptase inhibitors (NRTIs) can be combined safely with Rescriptor. However, you should not take buffered Videx® (ddI) tablets—or anything containing an antacid—within one hour of a dose of Rescriptor. Both antacids and Videx tablets (which contain an antacid) can block Rescriptor from being absorbed into the bloodstream.
- Rescriptor can increase the blood levels of all of the available protease inhibitors. In turn, the dose of the protease inhibitor being used may need to be decreased.
- If you take methadone, Rescriptor may increase the amount of it in your blood. It might be necessary to change your dose of methadone if you combine it with Rescriptor.
- Cholesterol-lowering drugs, also known as “statins,” can interact with Rescriptor. There are two statins that should not be used with Rescriptor: Zocor® (simvastatin) and Mevacor® (lovastatin). Levels of these two drugs can become significantly increased

in the bloodstream if they are combined with Rescriptor, which increases the risk of side effects. The two statins that are considered to be the safest in combination with Rescriptor are Pravachol® (pravastatin) and Lescol® (fluvastatin). It is also possible to take Rescriptor with Lipitor® (atorvastatin), although Rescriptor can increase Lipitor levels in the bloodstream. If Lipitor is prescribed, it's best to begin treatment with the lowest possible dose of the drug and then increase the dose if necessary. Little is known about the newest statin, Crestor® (rosuvastatin), although it is not expected to have any serious drug interactions with Rescriptor.

- Rescriptor can interact with some medications used to treat TB, MAC and other bacterial infections. Rifadin® (rifampin) can decrease Rescriptor levels (these two drugs should not be used together). Rescriptor can increase Mycobutin® (rifabutin) levels and Mycobutin can decrease Rescriptor levels (these two drugs should not be used together). Rescriptor can also increase Biaxin® (clarithromycin) levels and Biaxin can decrease clarithromycin levels (if Biaxin must be used, your doctor should monitor your kidneys carefully).
- It is not known if Rescriptor interacts with oral contraceptives/birth control pills (ethinyl estradiol).
- Blood levels of Viagra® (sildenafil) and Levitra® (vardenafil), two drugs used for erectile dysfunction, can increase if they are combined with Rescriptor. In turn, it is best to use a lower dose of these drugs in order to reduce the risk of side effects.

What is known about side effects?

- The most common side effect of Rescriptor is skin rash. In clinical trials, approximately one of every four (25%) HIV-positive people who took the drug developed a rash. Most of these cases involved either mild or moderate rash—the rashes either improved on their own or were managed using a

mild steroid cream or oral medication. If you experience rash while taking Rescriptor, be sure to report it to your doctor.

- In a small number of patients, rash has been serious and resulted in death. Therefore, if you develop a rash with any of the following symptoms, call your doctor immediately: general ill feeling, fever, muscle or joint aches, blisters, mouth sores, conjunctivitis (inflammation of the inner surface of the eyelids), swelling of the face, tiredness.
- If you must stop treatment with Rescriptor because you have these types of serious reactions, you must not take the drug again.
- Other possible side effects include nausea, diarrhea, headache, and fatigue.

Can pregnant women take Rescriptor?

- Rescriptor is classified by the FDA as a pregnancy category C drug. All the FDA-approved anti-HIV drugs are classified as either category B or C. Pregnancy category B means that animal studies have failed to demonstrate a risk to the fetus, but there are no adequate and well-controlled studies in pregnant women. Pregnancy category C means that animal studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks. HIV-positive women who become pregnant should discuss the benefits and possible side effects of anti-HIV treatment to help protect their babies from HIV.
- It is not known if Rescriptor can pass from a mother to her baby through breast milk. It is also not known what effect this may have on a nursing baby. To prevent transmission of the virus to uninfected babies, it is recommended that HIV-positive mothers not breast-feed.



For more treatment information, call Project Inform's toll-free National HIV/AIDS Treatment Information Hotline at 1-800-822-7422.

Who should not take Rescriptor?

- Do not take Rescriptor if you are allergic to it or any of its ingredients.
- Do not restart Rescriptor after you recover from serious skin reactions which have occurred while taking this drug.

Where can I learn more about clinical trials of Rescriptor?

- Even though Rescriptor is approved for the treatment of HIV, it is still used in clinical trials, either to learn more about its safety and effectiveness or

to determine how well it works in combination with experimental treatments.

- If you would like to find out if you are eligible for any clinical trials that include Rescriptor, there is an interactive web site run by amfAR, the American Foundation for AIDS Research.
- Another useful service for finding clinical trials is *AIDSinfo.nih.gov*, a site run by the U.S. National Institutes of Health. They have “health information specialists” you can talk to at their toll-free number at 1-800-HIV-0440 (1-800-448-0440).

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