

RESCRIPTOR[®] **(delavirdine mesylate) tablets**

ALERT: Find out about medicines that should NOT be taken with RESCRIPTOR. Please also read the section “**MEDICINES YOU SHOULD NOT TAKE WITH RESCRIPTOR.**”

Patient Information

RESCRIPTOR[®] (ree-SKRIP-tor)

Generic name: delavirdine mesylate (de-LAH-vur-deen MESS-ihl-ate)

Read this information carefully before taking RESCRIPTOR. Also, read this leaflet each time you renew the prescription, just in case anything has changed. This is a summary and not a replacement for a careful discussion with your healthcare provider (doctor, nurse, pharmacist). You and your healthcare provider should discuss RESCRIPTOR when you start taking this medication and at regular checkups. You should remain under a doctor's care when taking RESCRIPTOR and should not change or stop treatment without first talking with your healthcare provider.

What is RESCRIPTOR and how does it work?

RESCRIPTOR is a medicine used in combination with other anti-HIV medicines to treat people with HIV infection. Infection with HIV leads to the destruction of infection-fighting immune system cells (called CD₄ cells or T cells), which are important to the immune system. After a large number of CD₄ cells have been destroyed, the infected person develops acquired immune deficiency syndrome (AIDS).

RESCRIPTOR helps to block HIV reverse transcriptase, a chemical the virus uses to make more copies of itself. The main goals of anti-HIV medicines like RESCRIPTOR are to decrease the amount of virus in your blood (called viral load) and to increase the number of CD₄ cells as much as possible for as long as possible.

RESCRIPTOR, when taken with other anti-HIV medicines, lowers the HIV viral load in patients. Patients who took RESCRIPTOR as part of combination therapy for HIV also had increases in their CD₄ cell count.

Does RESCRIPTOR cure HIV or AIDS?

RESCRIPTOR is not a cure for HIV infection or AIDS. People taking RESCRIPTOR may still develop opportunistic infections or other conditions associated with HIV infection. Opportunistic infections are infections that develop because the immune system is weak. Some of these conditions are pneumonia, herpes virus infections, *Mycobacterium avium* complex (MAC) infections, and Kaposi's sarcoma.

Does RESCRIPTOR reduce the risk of passing HIV to others?

RESCRIPTOR does not reduce the risk of transmitting HIV to others through sexual contact or blood contamination. Continue to practice safe sex and do not use or share dirty needles.

How should I take RESCRIPTOR?

- You should stay under a healthcare provider's care when taking RESCRIPTOR. Do not change your treatment or stop treatment without first talking with your healthcare provider.
- You must take RESCRIPTOR every day exactly as your healthcare provider prescribed it. Follow the directions from your healthcare provider, exactly as written on the label.
- **The usual dose of RESCRIPTOR is two 200 mg tablets three times a day or four 100 mg tablets three times a day, in combination with other anti-HIV medicines. Either way, your total daily dose of RESCRIPTOR remains the same.**
- You can take RESCRIPTOR with or without food.
- If you have trouble swallowing tablets, the 100 mg RESCRIPTOR tablets may be dissolved in water. Place four tablets in at least 3 ounces of water and allow the tablets to sit in the water for a few minutes. Then, stir the water until the tablets have dissolved and drink the mixture right away. Add a little more water, swirl, and then drink the rest of the mixture to be sure that you get all the medicine. **The 200 mg tablets must be swallowed whole. They cannot be dissolved in water.**
- Many people find it easier to take their RESCRIPTOR with breakfast, lunch, and dinner, since food does not interfere with RESCRIPTOR. It is a good idea to get into the habit of taking RESCRIPTOR on a regular schedule to make it easier to remember. Figure out things that happen every day at pill-taking time and take your tablets then. By taking your medicine along with activities you do every day, such as getting up in the morning, brushing your teeth, eating lunch, coming home from work in the evening, or watching a favorite TV show, you will find it easier to remember to take every dose.
- When your RESCRIPTOR supply starts to run low, get more from your healthcare provider or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to RESCRIPTOR and become harder to treat.
- Only take medicine that has been prescribed specifically for you. Do not give RESCRIPTOR to others or take medicine prescribed for someone else.

What should I do if I miss a dose of RESCRIPTOR?

If you forget to take a dose of RESCRIPTOR, take it as soon as possible. However, if you skip the dose entirely, do not double the next dose. If you forget a lot of doses, talk to your healthcare provider about how you should continue taking your medicine.

Who should not take RESCRIPTOR?

Together with your healthcare provider, you need to decide whether RESCRIPTOR is right for you.

- **Do not take RESCRIPTOR if you are taking certain medicines.** These could cause serious side effects that could cause death. Before you take RESCRIPTOR, you must tell your healthcare provider about all the medicines you are taking or are planning to take. These include other prescription and nonprescription medicines and herbal supplements.

For more information about medicines you should not take with RESCRIPTOR, please read the section titled “**MEDICINES YOU SHOULD NOT TAKE WITH RESCRIPTOR.**”

- **Do not take RESCRIPTOR if you have an allergy to RESCRIPTOR.** Also tell your healthcare provider if you have any known allergies to other medicines, foods, preservatives, or dyes.
- **Tell your healthcare provider if you are pregnant or plan to become pregnant.** The effects of RESCRIPTOR on pregnant women or their unborn babies are not known.
- If you are breast-feeding, it is very important that you speak with your healthcare provider about the best way to feed your baby. If your baby does not already have HIV, there is a chance that it can be transmitted through breast-feeding. **The Centers for Disease Control and Prevention recommends that women with HIV do not breast-feed.**
- **Talk with your healthcare provider if you have liver or kidney disease.** RESCRIPTOR has not been studied in people with liver or kidney disease.
- **Certain medical problems may affect the use of RESCRIPTOR.** Be sure to tell your healthcare provider of any other medical problems you may have.

Can I take RESCRIPTOR with other medicines?

RESCRIPTOR may interact with other medicines, including those you take without a prescription. You must tell your healthcare provider about all medicines you are taking or planning to take before you take RESCRIPTOR. It is a good idea to keep a complete list of all the medicines that you take, including nonprescription medicines, herbal remedies and supplements and street drugs. Update this list when medicines are added or stopped. Give copies of this list to all of your healthcare providers **every** time you visit or fill a prescription.

MEDICINES YOU SHOULD NOT TAKE WITH RESCRIPTOR

Do not take the following medicines with RESCRIPTOR because they can cause serious problems or death if taken with RESCRIPTOR:

- Versed[®] (midazolam) Injection and Syrup (for sedation)
- Halcion[®] (triazolam) Tablets (for sleep problems)
- Xanax[®] (alprazolam) Tablets (for anxiety)
- D.H.E. 45[®] Injection, Ergomar[®], Migranal[®], Wigraine[®] and Cafergot[®] (for migraine headaches)
- Methergine[®] (for bleeding after childbirth)
- Orap (pimozide) Tablets (for seizures)
- Propulsid (cisapride) Tablets and Suspension (for heartburn)
- Hismanal[®] (astemizole) Tablets (for allergies)
- Seldane[®] (terfenadine) Tablets (for allergies)

Do not take the following medicines when you take RESCRIPTOR. They may reduce the levels of RESCRIPTOR in the blood and make it less effective. Talk with your healthcare provider if you are currently taking these medicines because other medicines may have to be given to take their place:

- Rifampin (also known as Rimactane[®], Rifadin[®], Rifater[®], Rifamate[®]) (to treat tuberculosis)
- Phenobarbital (for seizures)
- Dilantin[®] (phenytoin) (for seizures)
- Tegretol[®] (carbamazepine) (for seizures)

Do not take RESCRIPTOR with St. John's wort (*hypericum perforatum*), an herbal product sold as a dietary supplement, or products containing St. John's wort. Talk with your healthcare provider if you are taking or planning to take St. John's wort. Taking St. John's wort may decrease RESCRIPTOR levels and lead to increased viral load and possible resistance to RESCRIPTOR or cross-resistance to other anti-HIV medicines.

Do not take RESCRIPTOR with cholesterol-lowering medicines Mevacor[®] (lovastatin) or Zocor[®] (simvastatin) because of possible serious reactions. There is also an increased risk of drug interactions between RESCRIPTOR and Lipitor[®] (atorvastatin), Baycol[®] (cerivastatin) and Lescol[®] (fluvastatin); talk to your healthcare provider before you take any of these cholesterol-reducing medicines with RESCRIPTOR.

Medicines that require dosage adjustments:

It is possible that your healthcare provider may need to increase or decrease the dose of other medicines when you are taking RESCRIPTOR. Remember to tell your healthcare provider all the medicines you are taking or planning to take.

Before you take Viagra[®] (sildenafil) with RESCRIPTOR, talk to your healthcare provider about problems these two medicines can cause when taken together. You may get increased side effects of Viagra, such as low blood pressure, vision changes, and penis erection lasting more than 4 hours. If an erection lasts longer than 4 hours, get medical help right away to avoid permanent damage to your penis. Your healthcare provider can explain these symptoms to you.

- **If you are taking both Videx[®] (didanosine, dDI) and RESCRIPTOR:**
Take Videx (buffered tablets) 1 hour before or 1 hour after you take RESCRIPTOR. Taking them together causes lower amounts of RESCRIPTOR in the blood, making both medicines less effective.
- **Protease inhibitors:** A number of healthy volunteers and HIV-infected patients were studied while taking RESCRIPTOR with one of these protease inhibitors: Crixivan[®] (indinavir), Invirase[®] and Fortovase[®] (saquinavir), Norvir[®] (ritonavir), or VIRACEPT[®] (nelfinavir). RESCRIPTOR was shown to increase the amount of these protease inhibitors in the blood. RESCRIPTOR is expected to increase the amount of Agenerase[®] (amprenavir) and Kaletra[®] (lopinavir + ritonavir) in the blood. **As a result, your healthcare provider may choose to lower the dose of one of these medicines or monitor certain lab tests if these protease inhibitors are taken in combination with RESCRIPTOR.**
- **Antacids** should be taken at least 1 hour before or 1 hour after you take RESCRIPTOR because they can slow the absorption of RESCRIPTOR.

Based on your history of taking other anti-HIV medicine, your healthcare provider will direct you on how to take RESCRIPTOR and other anti-HIV medicines. These drugs should be taken in a certain order or at specific times. This will depend on how many times a day each medicine should be taken. It will also depend on whether the medicines should be taken with or without food.

What are the possible side effects of RESCRIPTOR?

- This list of side effects is not complete. If you have questions about side effects, ask your doctor, nurse, or pharmacist. You should report any new or continuing symptoms to your healthcare provider right away. Your healthcare provider may be able to help you manage these side effects.
- The most important common side effect seen in people taking RESCRIPTOR has been a skin rash. The rash occurs mainly on the upper body and upper arms, and sometimes on the neck and face. The rash appears as a red area on the skin with slight bumps, and it can be itchy. The rash tends to occur early, usually within 1 to 3 weeks after you start taking RESCRIPTOR, and it usually lasts less than 2 weeks. Watch your rash carefully and talk to your healthcare provider about how to treat it. If the rash is going to be serious or severe (with fever, blistering, sores in the mouth, redness or swelling of the eyes, or muscle and joint aches), you and your healthcare provider will usually realize it during the first 3 days of the rash. If you have symptoms of a severe rash, you should stop taking RESCRIPTOR and speak with your healthcare provider as soon as possible. Be prepared to explain where the rash is, your temperature, and whether or not you have other symptoms.
- Other side effects include headache, nausea, diarrhea, and tiredness. Of these, nausea was the most common.
- Changes in body fat have been seen in some patients taking antiretroviral therapy. These 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.
- Before you start using any medicine, talk with your healthcare provider about what to expect and discuss ways to reduce the side effects you may have.

How do I store RESCRIPTOR?

- Keep RESCRIPTOR and all other medicines out of the reach of children. Keep the bottle closed and store at room temperature (between 68°F and 77°F) away from sources of moisture such as a sink or other damp place. Heat and moisture may reduce the effectiveness of RESCRIPTOR.
- Do not keep medicine that is out of date or that you no longer need. Be sure that if you throw any medicine away, it is out of the reach of children.

General advice about prescription medicines:

Discuss all questions about your health with your healthcare provider. If you have questions about RESCRIPTOR or any other medicines you are taking, ask your healthcare provider. You can also call 1-888-847-2237 toll free.



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