

Rescriptor (delavirdine)



Delavirdine tablets are white, capsule-shaped, and marked with "U 3761."



Also known as: DLV, delavirdine mesylate, BHAP, U-90152

Background and description. Rescriptor is a non-nucleoside reverse transcriptase inhibitor (NNRTI), manufactured by Pharmacia & Upjohn. Recently Agouron Pharmaceuticals, now a division of Pfizer, acquired the commercial rights to Rescriptor. The drug was granted accelerated approval for use with other antiretroviral drugs by the FDA in April 1997.

Dose. The recommended dose of is 400 mg (four 100 mg tablets) 3 times a day. A dose can be dissolved in 3 ounces of water for ease of administration. Some studies currently use 600 mg twice a day.

Food restrictions. Rescriptor may be taken with or without food.

Storage. Rescriptor should be stored at a controlled room temperature of 68° to 77°F in a tightly closed container and protected from high humidity.

Patient assistance. Agouron/Pfizer offers a patient assistance program for those who qualify. For more information call 888.777.6637.

Side effects and toxicity. The most common side effect is a skin rash that usually lasts less than 2 weeks. In clinical stud-

ies, skin rash occurred in 18% of patients receiving the 400 mg dose of Rescriptor 3 times a day. The rash tends to occur early, usually within 1 to 3 weeks after initiating Rescriptor. Other side effects include headache, nausea, diarrhea, fatigue, and elevation of liver enzymes. Of these, nausea is the most commonly reported.

Drug interactions. Rescriptor should not be taken with the following: Xanax (alprazolam); Versed (midazolam); Halcion (triazolam); Carbatrol, Tegretol, or Tegretol XR (carbamazepine); Dilantin (phenobarbital, phenytoin); Propulsid (cisapride); Tagamet (cimetidine); Pepcid (famotidine); Axid (nizatidine); Zantac (ranitidine); Rifadin or Rimactane (rifampin); or Mycobutin (rifabutin). Caution should be used with Voriconazole (VFEND) when given with Rescriptor. Also, St. John's Wort (*Hypericum perforatum*) is likely to decrease Rescriptor levels in the body and therefore should be avoided when taking Rescriptor.

Antacids should be taken at least 1 hour before or after taking Rescriptor because they can slow the absorption of Rescriptor. Videx should be taken 1 hour before or after Rescriptor.

Rescriptor increases the blood levels of the protease inhibitors Fortovase, Norvir, Crixivan, and Viracept. Dosing adjustment may be required. No data with respect to its interaction with the protease inhibitor Agenerase have been reported.

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Additional info:

Resistance and cross-resistance. Resistance to Rescriptor emerges rapidly *in vitro* and when used as monotherapy. Resistance resulting in treatment failure is commonly associated with mutations at positions 103 and 181. The mutation at position 103 causes cross-resistance with all other approved NNRTIs.

Clinical data. Rescriptor was approved on the basis of 3 studies: Pharmacia & Upjohn Study 0021, Study 0017, and ACTG 261. None of the combinations in any of these studies are capable of achieving maximal viral suppression and since resistance develops rapidly to Rescriptor when used in suboptimal combinations, these studies showed little benefit from the use of Rescriptor.

Subsequent research reported at the 5th Conference on Retroviruses and Opportunistic Infections (Chicago, 1998) compared Rescriptor/Retrovir/Epivir against Retrovir/Epivir against Rescriptor/Retrovir. At 24 weeks the triple-combination arm had a significantly greater reduction in viral load (2.25 log) than the other 2 arms. Similarly, the percentage of patients in that arm having viral loads less than 400 copies/mL was significantly greater (71% at week 24) than the other 2 arms. CD4 T cell increase in the triple-drug arm was 105 cells/mm³ compared to 75 cells/mm³ in the Retrovir/Epivir arm and 3 cells/mm³ in the Rescriptor/Retrovir arm.

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