

Prior Authorization DRUG Guidelines

RESCRIPTOR (Delavirdine)

Effective Date: 1/28/14

Date Developed: 1/28/14 by Catherine Sanders, MD

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Rescriptor is an Antiretroviral Agent, Reverse Transcriptase Inhibitor (Non-nucleoside) used in the treatment of HIV-1 infection. Delavirdine binds directly to reverse transcriptase, blocking RNA-dependent and DNA-dependent DNA polymerase activities.

Pre-Authorization Criteria:

Rescriptor is used in patients with HIV-1 infection in combination with at least two additional antiretroviral agents. Due to rapid emergence of resistance, as only a single delavirdine mutation causes resistance, Rescriptor should not be used as monotherapy or as a component of an initial antiretroviral regimen. Cross resistance may be conferred to other non-nucleoside reverse transcriptase inhibitors, although potential for cross-resistance with protease inhibitors is low.

VCHCP requires that Rescriptor be prescribed by an Immunology Clinic physician with current American Academy of HIV Medicine (AAHIVM) certification or a physician boarded in Infectious Disease.

Dosing: Adult:

HIV-1 infection (part of combination): Oral: 400 mg 3 times/day

Dosing: Pediatric:

HIV-1 infection (part of combination): Adolescents ≥ 16 years: Refer to adult dosing.

Administration:

Patients with achlorhydria should take the drug with an acidic beverage; antacids and delavirdine should be separated by 1 hour. A dispersion of delavirdine may be prepared by adding four 100 mg tablets to at least 3 oz of water. Allow to stand for a few minutes and stir until uniform dispersion. Drink immediately. Rinse glass and mouth, then swallow the rinse to ensure total dose administered. The 200 mg tablets should be taken intact.

Dosing: Geriatric:

Refer to adult dosing.

Dosing: Renal Impairment:

No dosage adjustment provided in manufacturer's labeling (has not been studied).

Dosing: Hepatic Impairment:

No dosage adjustment provided in manufacturer's labeling (has not been studied). However, delavirdine is primarily metabolized by the liver, use with caution.

Dosage Forms: U.S.:

Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Tablet, Oral, as mesylate:

Rescriptor: 100 mg, 200 mg

Generic Equivalent Available: U.S.-No

Exclusions:

Rescriptor is not to be used as monotherapy.

Rescriptor is not to be used as a component of an initial antiretroviral regimen.

Contraindications:

Hypersensitivity to delavirdine or any component of the formulation; concurrent use of alprazolam, astemizole, cisapride, ergot alkaloids, midazolam, pimozide, rifampin, terfenadine, or triazolam

Adverse Reactions:

>10%: headache, depressive symptoms, fever, rash, nausea, vomiting.

Other Severe Less Common Reactions: Immune reconstitution syndrome, fat redistribution, angioedema, dyspnea, granulocytosis, leukopenia, pancytopenia, thrombocytopenia, hemolytic anemia, autoimmune disorders, pancreatitis, GI bleeding, cardiomyopathy, hepatic failure, acute renal failure, rhabdomyolysis.

References:

1. DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents, "Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents, Department of Health and Human Services," February 12, 2013;1-267. Available at <http://www.aidsinfo.nih.gov>
2. DHHS Panel on Opportunistic Infections (OI) in HIV-Infected Adults and Adolescents, "Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents: Recommendations from the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the HIV Medicine Association (HIVMA) of the Infectious Diseases Society of America (IDSA)," May 7, 2013. Available at http://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf
3. Hilts AE and Fish DN, "Dosage Adjustment of Antiretroviral Agents in Patients With Organ Dysfunction," *Am J Health Syst Pharm*, 1998, 55:2528-33. [PubMed 9853641]
4. Working Group on Antiretroviral Therapy and Medical Management of HIV-Infected Children, "Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection," August 16, 2010. Available at <http://www.aidsinfo.nih.gov>
5. www.uptodate.com: Delavirdine: Drug Information
6. www.epocrates.com: Rescriptor Drug Information

Revision History:

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