

FIRST TIME GENERIC APPROVAL

Brand Name	Selzentry
Generic Name	maraviroc
Drug Manufacturer	Camber Pharmaceuticals, Inc.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

February 7, 2022

LAUNCH DATE

February 14, 2022

REVIEW DESIGNATION

N/A

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 203347

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Maraviroc tablet is a CCR5 co-receptor antagonist indicated in combination with other antiretroviral agents for the treatment of only CCR5-tropic HIV-1 infection in adults and pediatric patients 2 years of age and older weighing at least 10 kg.

Limitations of Use: Not recommended in patients with dual/mixed- or CXCR4-tropic HIV-1.

MECHANISMS OF ACTION

Maraviroc is a member of a therapeutic class called CCR5 co-receptor antagonists. maraviroc selectively binds to the human chemokine receptor CCR5 present on the cell membrane, preventing the interaction of HIV-1 gp120 and CCR5 necessary for CCR5-tropic HIV-1 to enter cells. CXCR4-tropic and dual-tropic HIV-1 entry is not inhibited by maraviroc.

DOSE FORM AND STRENGTH

Tablets: 150 mg and 300 mg.

DOSE & ADMINISTRATION

- Prior to initiation of maraviroc tablets for treatment of HIV-1 infection, test all patients for CCR5 tropism using a highly sensitive tropism assay.
- Maraviroc tablets are taken twice daily by mouth and may be taken with or without food. maraviroc tablets must be given in combination with other antiretroviral medications.

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Recommended Dosage in Adult Patients:

Concomitant Medications	Dosage of Maraviroc tablets
When given with potent cytochrome P450 (CYP)3A inhibitors (with or without potent CYP3A inducers) including PIs (except tipranavir/ritonavir) (2.3, 7.1)	150 mg twice daily
With NRTIs, tipranavir/ritonavir, nevirapine, raltegravir, and other drugs that are not potent CYP3A inhibitors or CYP3A inducers (2.3, 7.1)	300 mg twice daily
With potent and moderate CYP3A inducers including efavirenz (without a potent CYP3A inhibitor) (2.3, 7.1)	600 mg twice daily

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