Maraviroc (MVC, Selzentry)

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Formulations

Oral Solution: 20 mg/mL

Tablets: 150 mg, 300 mg

For additional information, see Drugs@FDA or DailyMed.

Dosing Recommendations

- Maraviroc (MVC) is approved by the U.S. Food and Drug Administration for use, in combination with other antiretroviral (ARV) agents, for the treatment of CCR5-tropic HIV-1 infection in infants born full term and weighing ≥2 kg, children, adolescents, and adults.

Recommended MVC Dose for Full-Term Infants and Treatment-Experienced Children and Adolescents Weighing ≥2 kg: Tablets or Oral Solution

Weight Band	Twice-Daily Dosing	Oral Solution (20 mg/mL)	Tablets
Recommended doses when MVC is given with noninteracting drugs, such as nucleoside reverse transcriptase inhibitors (NRTIs), nevirapine (NVP), dolutegravir (DTG), and raltegravir (RAL)			
2 kg to <4 kg	30 mg	1.5 mL	N/A
4 kg to <6 kg	40 mg	2 mL	N/A
6 kg to <10 kg	100 mg	5 mL	N/A
10 kg to <14 kg	150 mg	7.5 mL	One 150-mg tablet
14 kg to <30 kg	200 mg	10 mL	N/A
≥30 kg	300 mg	15 mL	One 300-mg tablet

Selected Adverse Events

- Nausea, vomiting
- Abdominal pain, diarrhea
- Cough
- Upper respiratory tract infections
- Fever
- Rash
- Hepatotoxicity (which may be preceded by severe rash and/or other signs of systemic allergic reaction)
- Postural hypotension (generally seen in patients with severe renal insufficiency)
- Dizziness

Special Instructions

- MVC is recommended for use in patients who have only CCR5-tropic HIV-1. Before using MVC, conduct testing with an HIV tropism assay (see Drug-Resistance Testing in the Adult and Adolescent Antiretroviral Guidelines) to exclude the presence of CXCR4-tropic or mixed/dual-tropic HIV. Do not use MVC if CXCR4-tropic or mixed/dual-tropic HIV is present.
- Measure alanine aminotransferase, aspartate aminotransferase, and bilirubin prior to initiation of MVC and as clinically indicated while receiving MVC. Additional monitoring may be necessary for individuals with hepatitis B virus or hepatitis C virus coinfection or preexisting liver dysfunction.
- MVC can be given without regard to food.

Recommended doses when MVC is given with potent cytochrome P450 (CYP) 3A inhibitors (with or without a potent CYP3A inducer), including all protease inhibitors (PIs)			
2 kg to <10 kg	**Not recommended.** Data are insufficient to make dosing recommendations for infants weighing <10 kg and receiving a potent CYP3A inhibitor.		
10 kg to <20 kg	50 mg	2.5 mL	N/A
20 kg to <30 kg	75 mg	4 mL	N/A
30 kg to <40 kg	100 mg	5 mL	N/A
≥40 kg	150 mg	7.5 mL	One 150-mg tablet
Recommended doses when MVC is given with potent CYP3A inducers (without a potent CYP3A inhibitor), including efavirenz (EFV) and etravirine (ETR)			
Infants and children and adolescents in all weight bands	**Not recommended.** Data are insufficient to make dosing recommendations.		

Recommended MVC Dose for Adults: Tablets

When Coadministered With	Dose
Noninteracting concomitant medications, including NRTIs, NVP, DTG, and RAL	300 mg twice daily
Potent CYP3A inhibitors (with or without a potent CYP3A inducer), including all PIs	150 mg twice daily
Potent CYP3A inducers (without a potent CYP3A inhibitor), including EFV and ETR	600 mg twice daily

- Instruct patients on how to recognize symptoms of allergic reactions or hepatitis.
- Use caution when administering MVC to patients with underlying cardiac disease.

Metabolism/Elimination

- MVC is a substrate of CYP3A4. If a patient is receiving ARV agents or other medications that act as CYP3A inducers or inhibitors, the dose of MVC should be adjusted accordingly.

MVC Dosing in Patients With Hepatic Impairment

- Use caution when administering MVC to patients with hepatic impairment; MVC concentrations may be increased in these patients.

MVC Dosing in Patients With Renal Impairment

- No data recommend specific doses of MVC for pediatric patients with mild or moderate renal impairment. MVC is **contraindicated** for pediatric patients with severe renal impairment or end-stage renal disease (creatinine clearance <30 mL/min or who are receiving regular hemodialysis) and who are concomitantly receiving potent CYP3A inhibitors or inducers.
- Refer to the manufacturer's prescribing information for the appropriate doses to use in adolescent and adult patients with renal impairment (See Appendix B in the Adult and Adolescent Antiretroviral Guidelines.

Drug Interactions

Additional information about drug interactions is available in the Adult and Adolescent Antiretroviral Guidelines and the HIV Drug Interaction Checker.

- *Absorption:* Absorption of maraviroc (MVC) is slightly reduced with ingestion of a high-fat meal. Food restrictions were not part of either the adult trials (which used the tablet formulation) or the pediatric trial (which used both the tablet and oral solution formulations) that demonstrated the efficacy, antiviral activity, and safety of MVC. Therefore, MVC can be given with or without food.

- *Metabolism:* MVC is a cytochrome P450 (CYP) 3A and P-glycoprotein (P-gp) substrate and requires dose adjustments when administered with medications that modulate CYP3A or P-gp. A patient's medication profile should be carefully reviewed for potential drug interactions before MVC is administered; recommended MVC doses are based on concomitant medications and their anticipated effect on MVC metabolism. Particular attention should be paid to antimycobacterial and antiseizure agents, which may substantially decrease MVC levels (See Drug-Drug Interactions in the Adult and Adolescent Antiretroviral Guidelines). Concomitant use of MVC and St. John's wort (*Hypericum perforatum*) **is not recommended** because it may result in suboptimal levels of MVC.

Major Toxicities

- *More common:* Cough, fever, upper respiratory tract infections, rash, musculoskeletal symptoms, abdominal pain, vomiting, diarrhea, and headache. Dizziness or postural hypotension occurred in 12.2% of adults but only 3.2% of children when MVC was administered twice daily.
- *Less common (more severe):* Hepatotoxicity has been reported; some cases were preceded by evidence of a systemic allergic reaction (including pruritic rash, eosinophilia, or elevated levels of immunoglobulin E). Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug rash with eosinophilia and systemic symptoms (or DRESS) have been reported. Serious adverse events (AEs) occurred in <2% of MVC-treated adult patients and included cardiovascular abnormalities (e.g., angina, heart failure, myocardial infarction), hepatic cirrhosis or failure, cholestatic jaundice, viral meningitis, pneumonia, myositis, osteonecrosis, and rhabdomyolysis.

Mechanism of Action

MVC is a CCR5 receptor antagonist that selectively binds to the human chemokine receptor CCR5 on the cell membrane, preventing interaction between HIV-1 glycoprotein 120 and CCR5-tropic HIV-1, inhibiting viral entry into the cell.

Resistance

An HIV tropism assay should be performed before MVC is administered, and MVC should only be used for patients with CCR5-tropic HIV. Clinical failure on MVC may represent the outgrowth of preexisting, undetected CXCR4-tropic (naturally resistant) HIV variants. In addition, HIV-1 variants have been identified with amino acid substitutions that confer reduced susceptibility to MVC despite remaining CCR5-tropic. However, clinically available genotypic resistance testing typically does not report susceptibility to MVC.

In circumstances when MVC is needed for presumptive HIV therapy for full-term neonates at high risk of perinatal HIV transmission, initiation of MVC should not be deferred until tropism assay results are available; consultation with an HIV expert is recommended.

Pediatric Use

Approval

MVC is approved by the U.S. Food and Drug Administration (FDA) for treatment of CCR5-tropic HIV virus, when used in conjunction with other antiretroviral (ARV) drugs, in full-term infants weighing ≥2 kg, children, adolescents, and adults.[1,2]

Pharmacokinetics and Efficacy

The International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) 2007 study evaluated the pharmacokinetics (PK) and safety of MVC added to a 6-week prophylactic ARV regimen to prevent perinatal HIV transmission among infants born to mothers with HIV.[2] Analyses were stratified by exposure to efavirenz (EFV), either *in utero* or through breastmilk, versus non-EFV exposure. The MVC exposure target was average plasma concentration (C_{avg}) ≥75 ng/mL, as determined by adult treatment studies. MVC oral solution was dosed at 8 mg/kg twice daily for the first 6 weeks of life. Among 25 infants with evaluable PK data, 12 of whom were EFV-exposed, 67% of the EFV-exposed infants achieved a C_{avg} ≥75 ng/mL at Week 1, whereas 77% of the EFV-unexposed infants had a C_{avg} ≥75 ng/mL. At Week 4, the proportion of infants achieving a C_{avg} ≥75 ng/mL declined to 42% among EFV-exposed infants and 31% among EFV-unexposed infants. No infants in the study met safety endpoints or discontinued MVC during the study, and no infants acquired HIV. A population PK model, which included assessment of age and maturational changes, was developed from IMPAACT 2007 data to describe MVC disposition within the first 6 weeks of life.[3] Simulations with FDA-approved weight-band dosing resulted in the majority of simulated patients (84.3%) achieving an average concentration of ≥75 ng/mL. The FDA recommendation for MVC dosing among children >6 weeks of life but younger than 2 years of age is based on modeling using PK data from the IMPAACT 2007 study. When considering the use of MVC for neonates and infants, a pediatric HIV specialist should be consulted.

PK, safety, and efficacy of MVC for treatment-experienced children ages 2 years to <18 years and weighing ≥10 kg, and who had plasma HIV RNA >1,000 copies/mL were examined in an international dose-finding and efficacy study (NCT00791700). Of the 103 children who participated in the study, all of whom had CCR5-tropic HIV, 51% had HIV-1 subtype C, 25% had subtype B, and 23% had other subtypes. In this trial, the MVC dose was based on body surface area and the composition of the patient's optimized background therapy. Most participants (87%) received MVC in combination with potent CYP3A inhibitors; 10 participants received MVC with noninteracting medications; and only 3 participants received MVC with CYP3A inducers (without CYP3A inhibitors). The key pharmacologic target (geometric mean C_{avg} >100 ng/mL) was achieved with both the tablet and oral solution formulation of MVC in 98% of the 50 participants who entered the safety and efficacy stage of the study.[4] Only two participants discontinued the study due to AEs. The most common MVC-related AEs through 48 weeks were diarrhea (20.3% of participants), vomiting (19.8% of participants), and upper respiratory infections (16.2% of participants). At Week 48, 48% of participants had HIV RNA <48 copies/mL. From a mean baseline plasma HIV RNA concentration of 4.4 $\log_{10}$ copies/mL, a decrease of ≥1.5 $\log_{10}$ occurred in all four age-based cohorts.[4] However, this study was not designed to evaluate efficacy, and most treatment failures were suspected to be related to adherence challenges.

References

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2. Rosebush JC, Best BM, Chadwick EG, et al. Pharmacokinetics and safety of maraviroc in neonates. *AIDS*. 2021;35(3):419-427. Available at: https://pubmed.ncbi.nlm.nih.gov/33252481.

3. Liyanage M, Nikanjam M, McFadyen L, et al. Maraviroc population pharmacokinetics within the first 6 weeks of life. *Pediatr Infect Dis J*. 2022;41(11):885-890. Available at: https://pubmed.ncbi.nlm.nih.gov/35980827.

4. Giaquinto C, Mawela MP, Chokephaibulkit K, et al. Pharmacokinetics, safety and efficacy of maraviroc in treatment-experienced pediatric patients infected with CCR5-tropic HIV-1. *Pediatr Infect Dis J*. 2018;37(5):459-465. Available at: https://pubmed.ncbi.nlm.nih.gov/29023357.