Maraviroc (Selzentry, MVC)

Updated: March 31, 2026
Reviewed: March 31, 2026

Summary

- No dose adjustments are required for maraviroc (MVC) during pregnancy. The dose of MVC should be determined after accounting for potential drug interactions with concomitantly administered medications, including antiretroviral (ARV) drugs.
- Clinical data are insufficient to characterize the risk for congenital anomalies associated with *in utero* exposure to MVC.
- No reproductive toxicity or teratogenicity concerns were identified in animal studies.

Human Studies in Pregnancy

Pharmacokinetics

A U.S.–European intensive pharmacokinetic (PK) study measured 12-hour PK profiles in the third trimester and at least 2 weeks postpartum of 18 women who were taking MVC as part of clinical care.[1] Sixty-seven percent of the women in the study were taking MVC 150 mg twice daily with a protease inhibitor, 11% took MVC 300 mg twice daily, and 22% took an alternative regimen. The geometric mean ratio for third-trimester area under the curve (AUC) versus postpartum AUC was 0.72 (90% confidence interval [CI], 0.60–0.88); the geometric mean ratio for maximum MVC concentration in the third trimester versus maximum MVC concentration postpartum was 0.70 (90% CI, 0.58–0.85). Despite an overall 30% decrease in MVC AUC during pregnancy and a 15% decrease in trough concentration (C_{trough}), C_{trough} exceeded the minimum target concentration of 50 ng/mL in all participants except for one woman who had a C_{trough} below 50 ng/mL during both pregnancy and the postpartum period. These data suggest that the standard adult dose adjusted for concomitant ARV drugs is appropriate in pregnancy. A review of interactions between ARV drugs and oral contraceptives found that it is safe to coadminister oral contraceptives with MVC.[2]

Placental and Breast Milk Passage

In a study of six mother–infant pairs, the median ratio of MVC concentration in cord blood–to-MVC concentration in maternal plasma was 0.33 (with a range of 0.03–0.56), indicating moderate placental transfer.[1] An *ex vivo* human placental cotyledon perfusion model demonstrated minimal placental passage of MVC.[3] This may be due to the activity of multiple transporters (e.g., multidrug resistance–associated protein 1, organic anion transporting polypeptide 1A2, organic anion transporting polypeptide 1B3) that drive MVC away from fetal circulation into placental tissue, as demonstrated in a closed-circuit perfusion study of MVC across human placental cotyledon.[4] Whether MVC is secreted into human milk is unknown.

Teratogenicity/Adverse Pregnancy Outcomes

The Antiretroviral Pregnancy Registry (APR) provides updated birth defect data for MVC and other ARV drugs twice a year through an interim report released in June and December. For the most recent data about MVC, refer to Table 5. Number of Birth Defects by Trimester of Earliest Exposure to Each Drug in the current APR interim report. Available data are limited and insufficient for drawing conclusions about the risk of birth defects among infants who were exposed to MVC.

Other Safety Information

A retrospective study from an English–Irish cohort of 857 pregnant women showed an increased rate of hepatotoxicity among the 492 women who started ARV therapy during pregnancy.[5] MVC, efavirenz, and nevirapine were associated with an increased risk of liver enzyme elevation during pregnancy; the adjusted hazard ratio for MVC was 4.19 (range 1.34–13.1, $P = 0.01$). In a model that used human placental BeWo cells, MVC inhibited transplacental passage of two fluorescent organic cations, suggesting that MVC might influence placental drug transfer and cause drug–drug interactions.[6]

Animal Studies

Carcinogenicity

MVC was neither mutagenic nor clastogenic in a series of *in vitro* and animal *in vivo* screening tests. Long-term carcinogenicity studies of MVC in rats showed no drug-related increases in tumor incidence at exposures that were approximately 11 times those observed in humans who received the therapeutic dose.

Reproduction/Fertility

No adverse effects were observed on the fertility of male or female rats at doses of MVC that produced exposures (based on AUC) up to 20-fold higher than those seen in humans given the recommended 300-mg, twice-daily dose.

Teratogenicity/Adverse Pregnancy Outcomes

In animal reproduction studies, no evidence of adverse developmental outcomes was observed in animals that received MVC. During organogenesis in the rat and rabbit, systemic exposures to MVC (based on AUC) were approximately 20 times (in rats) and 5 times (in rabbits) the exposure seen in humans given the recommended 300-mg, twice-daily dose. In a rat prenatal and postnatal development study, maternal MVC AUC was about 14 times the exposure observed in humans given the recommended 300-mg, twice-daily dose.[7]

Placental and Breast Milk Passage

A study in rhesus macaques showed that single-dose MVC had low placental transfer and rapid clearance from infant monkeys 'blood.[8] Studies in lactating rats indicate that MVC is secreted extensively into rat milk.[7]

Excerpt From Table 14

Generic Name (Abbreviation) *Trade Name*	**Formulation**	**Dosing Recommendations**[a]	**Use in Pregnancy**
Maraviroc (MVC) *Selzentry*	**Tablets** • 150 mg[c] • 300 mg[c] • Solution • 20 mg/mL	**Pregnancy** *PK in Pregnancy* • A PK study in human pregnancy demonstrated a 20% to 30% overall decrease in MVC AUC, but C_{trough} exceeded the recommended minimum concentration of 50 ng/mL. *Dosing in Pregnancy* • Adjusting the standard adult MVC dose for concomitant use with ARV drugs seems appropriate. **Standard Adult Doses** • MVC 300 mg twice daily with or without food • MVC should be used only for patients with CCR5-tropic virus (and no X4-tropic virus). **Dose Adjustments** • Increase to MVC 600 mg twice daily when used with the potent CYP3A inducers EFV, ETR, and rifampin. • Decrease to MVC 150 mg twice daily when used with CYP3A inhibitors, which include all PIs except TPV/r and itraconazole.	Moderate placental transfer to fetus[b] No evidence of teratogenicity in rats or rabbits; insufficient data to assess teratogenicity in humans **Note:** Please see FDA label for full list of drugs with potential interactions and drugs for which administration with MVC is contraindicated.

[a] Individual ARV drug doses may need to be adjusted in patients with renal or hepatic insufficiency (for details, see the Adult and Adolescent Antiretroviral Guidelines, Appendix B).

[b] Placental transfer categories are determined by mean or median cord blood–to–maternal delivery plasma drug ratio:

High: >0.6
Moderate: 0.3–0.6
Low: <0.3

[c] Generic product is available.

Key: ARV = antiretroviral; AUC = area under the curve; CCR5 = C-C chemokine receptor type 5; C_{trough} = trough concentration; CYP = cytochrome P450; EFV = efavirenz; ETR = etravirine; MVC = maraviroc; PI = protease inhibitor; PK = pharmacokinetic; TPV/r = tipranavir/ritonavir

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