## DRUG INTERACTIONS WITH CCR5 ANTAGONISTS

| | Maraviroc, MVC, Celsentri® (Pfizer) | Cenicriviroc |
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| Dose | 150-600 mg BID, depending on concomitant medications | 50-200 mg QD under study |
| Metabolism | 3A4, Pgp | 3A4, 2C8 |
| Food Effect | ↓ 33% AUC with high fat meal | |
| **Interactions with Antiretrovirals:** | | |
| Atazanavir | When maraviroc 300 mg BID was given with atazanavir 400 mg QD, maraviroc AUC ↑ 3.6-fold, Cmax ↑ 2.1-fold, Cmin ↑ 4.2-fold. Reduction of maraviroc dose by 50% in the presence of protease inhibitors/potent CYP3A4 inhibitors is recommended.[1] | |
| Atazanavir/ritonavir | When maraviroc 300 mg BID was given with atazanavir 300/ritonavir 100 mg QD, maraviroc AUC ↑ 4.9-fold, Cmax ↑ 2.7-fold, Cmin ↑ 6.7-fold. Reduction of maraviroc dose by 50% in the presence of protease inhibitors/potent CYP3A4 inhibitors is recommended.[1]<br><br>In 15 HIV-positive patients who received maraviroc 150 mg plus atazanavir 300/100 mg daily as part of a PK substudy of a randomized 48 week trial comparing MVC/ATVr vs ATVr + TDF/FTC, adequate maraviroc exposures were achieved at week 2: AUC 4330 ng.h/mL, Cavg 180 ng/mL, Cmax 650 ng/mL, Cmin 37 ng/mL. All subjects achieved the targeted Cavg >75 ng/mL for near maximal virologic efficacy based upon exposure-response analysis from the MERIT study.[2] Week 24 interim analysis results of the randomized trial showed similar outcomes in both arms.[3]<br><br>Modeling of maraviroc kinetics showed that **maraviroc 150 mg QD plus ATV 300/100 mg QD** in HIV-positive subjects yielded lower Cmax and Cavg but higher Cmin and effective constant concentrations compared to maraviroc 300 mg BID alone in healthy volunteers.[4] | Cenicriviroc was administered at 50 mg once daily alone, or in combination with atazanavir 300/100 mg once daily for 10 days in healthy subjects.<br><br>In the presence of boosted atazanavir, cenicriviroc Cmax ↑ 155%, Cmin ↑ 475% and AUC0–24 ↑ 289%, compared to cenicriviroc administered alone. CVC alone and with ATV/r was generally well tolerated and no serious or unexpected adverse events were reported. Hyperbilirubinemia was observed following co-administration of ATV/r with CVC, and resolved after completion of dosing.[5] |
| AZT/3TC | In healthy volunteers, Combivir 1 tab BID + maraviroc 300 mg BID/placebo for 7 days showed no clinically relevant effect on the kinetics of AZT/3TC.[6] | |
| Darunavir/ritonavir | In healthy subjects, **maraviroc 150 mg** | Cenicriviroc was administered at 50 |

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| | **BID plus darunavir 600/ritonavir 100 mg BID** resulted in 2.3-fold ↑ Cmax, 4-fold ↑ AUC of maraviroc vs. maraviroc administered alone. Reduce maraviroc dose to 150 mg BID when coadministering with darunavir/ ritonavir.[7]<br><br>In a retrospective review, peak and trough levels were compared in HIV-positive patients taking either maraviroc 300 mg BID plus tenofovir/FTC, **maraviroc 300 mg QD plus darunavir 800/100 mg QD** or **maraviroc 150 mg QD plus darunavir 800/100 mg QD**. Maraviroc concentrations were comparable between the groups and all Ctrough >25 ng/mL. Cpeak did not exceed 1000 ng/mL and no cases of postural hypotension were noted. In the BID group, median Cpeak was 384 and Ctrough was 48 ng/mL, in the MVC 300 mg QD group, median Cpeak was 773 and Ctrough was 70 ng/mL, and in the MVC 150 mg QD group, median Ctrough was 50 ng/mL. All darunavir concentrations were therapeutic.[8]<br><br>See additional entry for **darunavir/ritonavir + etravirine plus maraviroc.** | mg once daily alone, or in combination with darunavir 800/100 mg once daily for 10 days in healthy subjects.<br><br>In the presence of boosted darunavir, cenicriviroc Cmax ↑ 117%, Cmin ↑ 317% and AUC0–24 ↑ 213%, compared to cenicriviroc administered alone. CVC alone and with DRV/r was generally well tolerated and no serious or unexpected adverse events were reported. No clinically relevant laboratory abnormalities were observed with CVC alone or in combination with DRV/r.[5]<br><br>In healthy volunteers, cenicriviroc 150 mg daily was administered alone or with darunavir 800/100 mg daily. In the presence of darunavir/ritonavir, cenicriviroc AUC, Cmax and Cmin increased by 3.13-, 2.17- and 4.17-fold, respectively, while plasma darunavir and ritonavir concentrations were not significantly affected. The combination was well-tolerated.[9] |
| Dolutegravir | | In healthy volunteers, coadministration of dolutegravir 50 mg daily and cenicriviroc 150 mg daily led to 29% ↓ AUC, 28% ↓ Cmax and 23% ↓ Cmin of cenicriviroc, and 14% ↑ AUC, 10% ↑ Cmax and 14% ↑ Cmin of dolutegravir. No dose adjustment of dolutegravir is required with coadministration; the reduction in cenicriviroc requires further investigation.[10] |
| Efavirenz | When maraviroc 100 mg BID was given with efavirenz 600 mg QD, maraviroc AUC ↓ 50%, Cmax ↓ 60%. Doubling maraviroc dose to 200 mg BID corrected maraviroc exposures. **When administering maraviroc with EFV (in the absence of PIs), doubling maraviroc dose is recommended**.[1]<br><br>An in vitro-in vivo extrapolation model was developed to describe the kinetics | In healthy subjects, coadministration of efavirenz 600 mg QD with CVC 200 mg QD resulted in 23% ↓ Cmax, 48% ↓ Cmin and 43% ↓ AUC of CVC compared to CVC 200 mg QD alone. When CVC 400 mg was coadministered with efavirenz, CVC Cmax ↑ 23%, Cmin ↓ 15% with no change in AUC compared to CVC 200 mg alone, and efavirenz exposure was not significantly different vs values when administered alone. |

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| | of maraviroc in HIV-infected patients switching from efavirenz-containing therapy. The model predicted that MVC exposures similar to those with MVC 300 mg BID alone could be achieved via two scenarios following a switch from EFV:<br>• MVC 600 mg BID x 1 week followed by standard 300 mg BID dosing<br>• MVC 450 mg BID x 2 weeks followed by standard BID dosing[11] | **Consider doubling dose of cenicriviroc when coadministering with efavirenz.**[12] |
| Elvitegravir/ritonavir | In a randomized, healthy subject study (n=28), volunteers received EVG/r 150/100mg QD for 10 days followed by EVG 150/100mg QD plus maraviroc 150mg BID for 10 days or vice versa. No clinically relevant changes in EVG/rtv kinetics were observed with the combination, while maraviroc exposures were ↑ in the presence of EVG/rtv (maraviroc AUC ↑ 2.15 fold, Cmax ↑ 2.86 fold).<br>Therefore, **reduce maraviroc dose to 150mg BID when used with EVG/r** (same as dose recommendation for MVC + other CYP 3A4 inhibitors).[13] | |
| Etravirine<br><br>*See additional entry for **darunavir/ritonavir + etravirine plus maraviroc.** | Total maraviroc concentrations over a 12-hour period are reduced by 53% ($AUC_{12}$) and peak levels of maraviroc ($C_{max}$) by 60% in the presence of etravirine.<br><br>Therefore, if a patient isn't also taking a potent CYP3A4 inhibitor such as RTV-boosted protease inhibitor, **maraviroc dose should be increased to 600mg twice daily**. No dose adjustment of etravirine is required.<br><br>In 64 HIV-positive patients taking maraviroc 300 or 600 mg BID plus etravirine 200 mg BID without PIs, 67% Ctrough were <75 ng/mL (75% with maraviroc 300 mg BID and 63% with maraviroc 600 mg BID). Mean maraviroc Ctrough was 53 and 60 ng/mL in the 300 and 600 mg BID groups, respectively. Etravirine Ctrough was 723 ng/mL, approximately 180-fold higher than the protein-adjusted EC50 for wild type virus[14] | |

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| | In a cohort of patients receiving maraviroc and raltegravir with or without etravirine, significantly lower maraviroc Ctrough were observed when combined with etravirine vs. without etravirine (57 vs 173.5 ng/mL respectively, p=0.01). Patients treated with maraviroc had significantly greater CD4 increases versus those not on maraviroc.[15] | |
| Fosamprenavir | In healthy volunteers, combination of maraviroc 300 mg BID plus fosamprenavir 1400 mg BID led to reduced concentrations of both drugs:[16]<br>• MVC AUC ↓13%, Cmax ↓ 11%, Cmin ↓28%<br>• APV AUC ↓ 44%, Cmax ↓ 51%, Cmin ↓ 1%<br>Data suggest that standard dose maraviroc may be used with fosamprenavir. | |
| Fosamprenavir/ ritonavir | In healthy volunteers, combination of maraviroc 300 mg BID plus fosamprenavir 1400/ritonavir 100 mg QD led to reduced concentrations of both drugs:[16]<br>• MVC AUC ↓2%, Cmax ↓ 7%, Cmin ↓23%<br>• APV AUC ↓ 21%, Cmax ↓ 32%, Cmin ↓ 36%<br>In same study, combination of maraviroc 300 mg BID plus fosamprenavir 700/ritonavir 100 mg BID led to:<br>• MVC AUC ↓66%, Cmax ↓ 70%, Cmin ↓54%<br>• APV AUC ↓ 26%, Cmax ↓ 31%, Cmin ↓ 24%<br>Need for MVC dose ↑ with FPV/r BID is unknown.[16]<br><br>In an open-label, fixed sequence study in healthy volunteers, cohort 1 received **maraviroc 300 mg BID** alone, **fosamprenavir 700/100 mg BID** alone, then the combination. With coadministration, maraviroc AUC ↑ 2.49 fold, Cmax ↑ 52% and Ctau ↑ 4.74-fold, while amprenavir AUC ↓ 35%, Cmax ↓ 34% and Ctau ↓ 36%. In cohort 2, volunteers received **maraviroc 300 mg QD** alone, | |

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| | **fosamprenavir 1400/100 mg QD** alone, then the combination. With coadministration, maraviroc AUC ↑ 2.26 fold, Cmax ↑ 45% and Ctau ↑ 1.8-fold, while amprenavir AUC ↓ 30%, Cmax ↓ 29% and Ctau ↓ 15%. The combination was well tolerated. Further investigation of maraviroc 300 mg QD with fosamprenavir 1400/100 mg QD is suggested.[17] | |
| Lamivudine | Maraviroc had no effect on the pharmacokinetics of lamivudine.[18] | |
| Lopinavir/ritonavir | When maraviroc 100 mg BID was given with lopinavir/ritonavir 400/100 mg BID, maraviroc AUC ↑ 3.8-fold, Cmax ↑ 1.8-fold, Cmin ↑ 9.2-fold. Reduction of maraviroc dose to 50 mg BID resulted in maraviroc AUC ↑ 1.6-fold.<br><br>**Maraviroc 50% dose reduction in the presence of protease inhibitors/potent CYP3A4 inhibitors is recommended**.[1]<br><br>When maraviroc was given as 150 mg QD with lopinavir/ritonavir 400/100 mg BID in HIV-infected subjects (n=10), median (IQR) maraviroc concentrations were as follows: $AUC_{24h}$ 4694 (3923-5516) hr*ng/ml, $C_{avg}$ 179 (159 -221) ng/ml, $C_{max}$ 601 (491-689) ng/ml, $C_{min}$ 59 (39-64) ng/ml. All 10 subjects achieved the targeted $C_{avg}$ (> 75 ng/ml).[19] | |
| Nevirapine | In a cohort of HIV+ subjects (n=8) stabilized on nevirapine, 3TC and tenofovir, kinetics of single dose maraviroc 300 mg were unchanged vs. control data in HIV+ subjects receiving maraviroc alone for 10 days.[20] | |
| Raltegravir | In an open-label, fixed sequence study, healthy subjects (n=18) received raltegravir 400 mg BID for 3 days, then maraviroc 300 mg BID for 6 days, then both drugs together for 3 days. Plasma drug concentrations were measured on the last day of each phase. When maraviroc and raltegravir were co-administered, mean maraviroc AUC ↓ 14% and Cmax ↓ 20% and mean raltegravir AUC ↓ 37% and Cmax ↓ 33% respective relative to each drug administered alone. The | |

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| | mechanism may be via decreased absorption or increase in first-pass metabolism.<br><br>The authors considered these changes not to be clinically significant, and dose adjustments are not suggested. Monitoring for safety and efficacy is recommended with this combination.[21] | |
| Ritonavir | When maraviroc 100 mg BID was given with ritonavir 100 mg BID, maraviroc AUC ↑ 2.6-fold, Cmax ↑ 1.3-fold. Reduction of maraviroc dose to 50 mg BID gave similar exposures as maraviroc 100 mg BID alone. Maraviroc 50% dose reduction in the presence of protease inhibitors/potent CYP3A4 inhibitors is recommended.[1] | Cenicriviroc was administered at 50 mg once daily alone, or in combination with ritonavir 100 mg once daily for 10 days in healthy subjects.<br><br>In the presence of ritonavir, cenicriviroc Cmax ↑ 139%, Cmin ↑ 424% and AUC0–24 ↑ 255%, compared to cenicriviroc administered alone. CVC alone and with ritonavir was generally well tolerated and no serious or unexpected adverse events were reported. No clinically relevant laboratory abnormalities were observed with CVC alone or in combination with ritonavir.[5] |
| saquinavir | When maraviroc 100 mg BID was given with saquinavir-sgc 1200 mg TID, maraviroc AUC ↑ 4.3-fold, Cmax ↑ 3.3-fold. Reduction of maraviroc dose by 50% in the presence of protease inhibitors/potent CYP3A4 inhibitors is recommended.[1] | |
| Saquinavir/ritonavir | When maraviroc 100 mg BID was given with saquinavir-sgc/ritonavir 1000/100 mg BID, maraviroc AUC ↑ 9.8-fold, Cmax ↑ 4.8-fold. Reduction of maraviroc dose to 25 mg BID resulted in maraviroc AUC ↑ 1.4-fold. Maraviroc 50% dose reduction in the presence of protease inhibitors/potent CYP3A4 inhibitors is recommended.[18] | |
| tenofovir | Maraviroc 300 mg BID did not affect kinetics of tenofovir 300 mg QD.[1] | |
| Tipranavir/ ritonavir | Combination of maraviroc 150 mg BID plus tipranavir 500/200 mg BID in healthy subjects did not lead to any significant changes in maraviroc exposures.[22] Regular dosing of maraviroc (i.e., 300 mg BID) may be used with tipranavir/ritonavir. | |
| Zidovudine | Maraviroc had no effect on the | |

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| | pharmacokinetics of zidovudine.[18] | |
| **Multi-ARV drug interactions:** | | |
| Darunavir/ritonavir + etravirine | Co-administration of **etravirine/darunavir/ritonavir** with maraviroc increased the exposure of maraviroc by 210% ($AUC_{12}$) and peak levels ($C_{max}$) by 77% compared to maraviroc alone.<br><br>Thus, if maraviroc is being dosed alongside etravirine and darunavir together, a maraviroc dose reduction to 150mg twice daily is necessary. No dose adjustment of ETV is necessary.[23] | |
| Efavirenz plus fosamprenavir/ ritonavir | | |
| Efavirenz plus lopinavir/ritonavir | When maraviroc 300 mg BID was given with lopinavir/ritonavir 400/100 mg BID plus efavirenz 600 mg QD, maraviroc AUC ↑ 2.5-fold, Cmax ↑ 1.3-fold, Cmin ↑ 6.3-fold vs. maraviroc alone.[18]<br><br>Maraviroc 150 mg BID dose recommended.[18] | |
| Efavirenz plus saquinavir/ritonavir | When maraviroc 100 mg BID was given with saquinavir-sgc/ritonavir 1000/100 mg BID plus efavirenz 600 mg QD, maraviroc AUC ↑ 5-fold, Cmax ↑ 2.3-fold, Cmin ↑ 8.4-fold vs. maraviroc alone.[18]<br><br>Maraviroc 150 mg BID dose recommended.[18] | |
| **Interactions with other medications:** | | |
| Digoxin | In healthy subjects who received maraviroc 300 mg BID for 6 days, the pharmacokinetics of single dose digoxin 0.25 mg were not altered in the presence of maraviroc compared to digoxin administered alone. This suggests that maraviroc is not a P-gp inhibitor and that dose adjustments are not required.[24] | |
| Hmg Co-A Reductase Inhibitors (statins) | CCR5 receptors, are located on cholesterol-rich 'lipid rafts' within cell membranes. Statins may reduce lipid raft numbers, potentially altering CCR5 availability and efficacy. A post-hoc analysis of the MOTIVATE studies | |

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| | assessed viral load and CD4 counts in 84 patients (of 840 total number of subjects) on statins (i.e., on statins at baseline and throughout study or at least 300 days).<br>There was no difference in mean VL reduction, % achieving <50 copies/mL and CD4 increases at 48 weeks between study subjects on vs. not on statins.[25] | |
| Ketoconazole | When given with ketoconazole 400 mg QD, maraviroc AUC ↑ 5-fold, Cmax ↑ 3.4-fold. Reduction of maraviroc dose by 50% in the presence of protease inhibitors/potent CYP3A4 inhibitors is recommended.[1] | |
| Midazolam | Maraviroc 300 mg BID had no effect on single-dose exposure of midazolam 7.5 mg.[1] | |
| Oral contraceptives | Maraviroc 100 mg BID had no effect on exposure of ethinylestradiol 30ug/levonorgestrel 150ug QD.[1] | |
| Phosphodiesterase-5 Inhibitors | No pharmacokinetic interaction is expected, as maraviroc does not inhibit CYP3A4. However, the PDE-5 inhibitors can decrease blood pressure and maraviroc doses >600 mg can increase the risk of postural hypotension. Maraviroc 300 mg BID should be administered with caution.[26]<br><br>In 18 healthy subjects who received maraviroc 300 mg BID for 3 days plus single-dose vardenafil 20 mg, no clinically significant additive declines in systolic or diastolic blood pressures (both standing and supine) were noted.[27] | |
| Rifampin | When maraviroc 100 mg BID was given with rifampin 600 mg QD, maraviroc AUC and Cmax ↓ 70%, Cmin ↓ 78%. Doubling maraviroc dose to 200 mg BID corrected maraviroc exposures.[1]<br><br>When administering maraviroc with rifampin, doubling maraviroc dose (to 600 mg BID) is recommended. | |
| Rifapentine | Reduction in maraviroc exposure anticipated with coadministration. **Avoid combination.**[28] | |
| Trimethoprim | Maraviroc 300 mg BID did not affect kinetics of trimethoprim 960 mg BID.[1] | |

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