

Table 9: Established and Other Potentially Significant Drug Interactions: Alteration in Dose or Regimen May Be Recommended Based on Drug Interaction Studies or Predicted Interaction

(See CLINICAL PHARMACOLOGY for Magnitude of Interaction, Tables 2 and 3)

Concomitant Drug Class: Drug Name	Effect on Concentration of lopinavir or Concomitant Drug	Clinical Comment
<i>HIV-Antiviral Agents</i>		
HIV-Protease Inhibitors: amprenavir*,	amprenavir (amprenavir 750 mg BID + KALETRA produces ↑ AUC, similar C _{max} , ↑ C _{min} , relative to amprenavir 1200 mg BID ↓ Lopinavir	Increase KALETRA dose to 533/133 mg and decrease amprenavir dose to amprenavir 750 mg BID, when coadministered. see DOSAGE AND ADMINISTRATION and CLINICAL PHARMACOLOGY : Tables 2 and 3.). Appropriate doses of the combination of fosamprenavir and Kaletra have not been established.
HIV-Protease Inhibitor: indinavir*	↑ indinavir (indinavir 600 mg BID + KALETRA produces similar AUC, ↓ C _{max} , ↑ C _{min} relative to indinavir 800 mg TID	Decrease indinavir dose to 600 mg BID, when coadministered with KALETRA 400/100 mg BID. (see CLINICAL PHARMACOLOGY : Table 3).
HIV-Protease Inhibitor: nelfinavir*	↑ nelfinavir (nelfinavir 1000 mg BID + KALETRA produces similar AUC, similar C _{max} , ↑ C _{min} relative to nelfinavir 1250 mg BID) ↑ M8 metabolite of nelfinavir ↓ Lopinavir	Increase KALETRA dose to 533/133 mg and decrease nelfinavir dose to 1000 mg BID, when coadministered. see DOSAGE AND ADMINISTRATION and CLINICAL PHARMACOLOGY : Tables 2 and 3.).
HIV-Protease Inhibitor: saquinavir*	↑ saquinavir (saquinavir 800 mg BID + KALETRA and saquinavir 1200 mg BID + KALETRA produces ↑ AUC, ↑ C _{max} , ↑ C _{min} relative to saquinavir 1200 mg TID)	Decrease saquinavir dose to 800 mg BID, when coadministered with KALETRA 400/100 mg BID. (see CLINICAL PHARMACOLOGY : Table 3).
<i>Other Agents</i>		
Antimycobacterial: Rifampin	↓ Lopinavir	May lead to loss of virologic response and possible resistance to KALETRA or to the class of protease inhibitors or other co administered antiretroviral agents. A study evaluated combination of rifampin 600 mg QD, with KALETRA 800/200 mg BID or KALETRA 400/100 mg + ritonavir 300 mg BID. Pharmacokinetic and safety results from this study do not allow for a dose recommendation. Nine subjects (28%) experienced a > grade 2 increases in ALT/AST, of which seven (21%) prematurely discontinued study per protocol. Based on the study design, it is not possible to determine whether the frequency or magnitude of the ALT/AST elevations observed is higher than what would be seen with rifampin alone. (See Clinical Pharmacology for magnitude of interaction, Table 2)

The Dosage and Administration section was updated to include dose adjustments for Kaletra with nelfinavir and amprenavir