

## Food Considerations for Antiretrovirals

Revised July 2019

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### Protease Inhibitors (PIs) (1/2)

Antiretroviral	Usual adult dose	Food requirements	Comments																									
<b>Atazanavir alone</b>	400 mg once daily	Should be taken with food	<p>Administration of atazanavir (400 mg single dose) with a light meal (357 kcal, 8.2g fat, 10.6 g protein) or a high-fat meal (721 kcal, 37.3 g fat, 29.4 g protein) had the following effects on pharmacokinetic parameters (relative to fasting):</p> <table> <thead> <tr> <th></th> <th>Light Meal</th> <th>High Fat Meal</th> </tr> </thead> <tbody> <tr> <td>AUC</td> <td>↑70%</td> <td>↑35%</td> </tr> <tr> <td>C<sub>max</sub></td> <td>↑57%</td> <td>↔</td> </tr> </tbody> </table> <p>Administration of atazanavir with either a light meal or high-fat meal decreased the coefficient of variation of AUC and C<sub>max</sub> by approximately one-half compared to the fasting state.</p>		Light Meal	High Fat Meal	AUC	↑70%	↑35%	C <sub>max</sub>	↑57%	↔																
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<b>Atazanavir/cobicistat</b>	300/150 mg once daily	Should be taken with food	<p>Administration of a single dose of atazanavir/cobicistat with either a light meal (336 kcal, 5.1 g fat, 9.3 g protein) or a high fat meal (1038 kcal, 59 g fat, 37 g protein) had the following effects on pharmacokinetic parameters (relative to fasting):</p> <table> <thead> <tr> <th></th> <th colspan="2">Light Meal</th> <th colspan="2">High Fat Meal</th> </tr> <tr> <th></th> <th>Atazanavir</th> <th>Cobicistat</th> <th>Atazanavir</th> <th>Cobicistat</th> </tr> </thead> <tbody> <tr> <td>AUC</td> <td>↑28%</td> <td>↑24%</td> <td>↓4%</td> <td>↑12%</td> </tr> <tr> <td>C<sub>max</sub></td> <td>↑42%</td> <td>↑31%</td> <td>↓14%</td> <td>↔</td> </tr> <tr> <td>C<sub>24</sub></td> <td>↑35%</td> <td>ND</td> <td>↑23%</td> <td>ND</td> </tr> </tbody> </table> <p>Atazanavir C<sub>max</sub> and AUCs after a high fat meal decreased 36% and 25% in comparison to a light meal, respectively, however, C<sub>24</sub> was similar.</p>		Light Meal		High Fat Meal			Atazanavir	Cobicistat	Atazanavir	Cobicistat	AUC	↑28%	↑24%	↓4%	↑12%	C <sub>max</sub>	↑42%	↑31%	↓14%	↔	C <sub>24</sub>	↑35%	ND	↑23%	ND
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C <sub>24</sub>	↑35%	ND	↑23%	ND																								
<b>Atazanavir/ritonavir</b>	300/100 mg once daily	Should be taken with food	<p>Administration of atazanavir/ritonavir (300/100 mg single dose) with a light meal or a high fat meal had the following effects on atazanavir pharmacokinetic parameters (relative to fasting):</p> <table> <thead> <tr> <th></th> <th>Light Meal</th> <th>High Fat Meal</th> </tr> </thead> <tbody> <tr> <td>AUC</td> <td>↑33%</td> <td>↔</td> </tr> <tr> <td>C<sub>max</sub></td> <td>↑40%</td> <td>11%</td> </tr> <tr> <td>C<sub>24</sub></td> <td>↑40%</td> <td>↑33%</td> </tr> </tbody> </table> <p>Administration with food decreased the coefficient of variation of AUC and C<sub>max</sub> by ~25% compared to the fasting state.</p>		Light Meal	High Fat Meal	AUC	↑33%	↔	C <sub>max</sub>	↑40%	11%	C <sub>24</sub>	↑40%	↑33%													
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<b>Darunavir/cobicistat</b>	<i>ARV-naïve patients and ARV-experienced patients (with no darunavir resistance, with plasma HIV-1 RNA &lt;100,000 copies/ml &amp; CD4 cell count ≥100):</i> 800/150 mg once daily	Should be taken with food	<p>Administration of darunavir/cobicistat to healthy adult subjects with a high-fat meal (965 total kcal: 129 kcal from protein, 236 kcal from carbohydrates and 600 kcal from fat) increased darunavir AUC and C<sub>max</sub> by 70% and 127%, when compared to fasted conditions. Cobicistat exposures were not affected by food.</p> <p>The type of food does not affect darunavir exposure.</p>																									
<b>Darunavir/ritonavir</b>	<i>ARV-naïve patients and ARV-experienced patients (with no darunavir resistance, with plasma HIV-1 RNA &lt;100,000 copies/ml &amp; CD4 cell count ≥100):</i> 800/100 mg once daily <i>Other ARV-experienced patients:</i> 600/100 mg twice daily	Should be taken with food	<p>Administration of darunavir/ritonavir with food increased darunavir C<sub>max</sub> and AUC by ~40% relative to the fasting state (total calorie content of the various meals evaluated ranged from 240 Kcal and 12 g fat to 928 Kcal and 56 g fat).</p> <p>The type of food does not affect darunavir exposure.</p>																									

Key: Can be taken with or without foodSpecific requirements for dosing relative to food intake

↑ Increase; ↓ decrease; ↔ no change; ND not determined

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## Food Considerations for Antiretrovirals

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### Protease Inhibitors (PIs) (2/2)

Antiretroviral	Usual adult dose	Food requirements	Comments
Fosamprenavir	Fosamprenavir 700 mg twice daily Ritonavir 100 mg twice daily	<b>Tablets:</b> Can be taken with or without food	Administration of fosamprenavir tablets (1400 mg single dose) with a high fat meal (967 kcal, 67 g fat, 33 g protein, 58 g carbohydrate) did not alter plasma amprenavir pharmacokinetics (C <sub>max</sub> , T <sub>max</sub> or AUC) when compared to the fasted state.
	<i>Additional options for ARV-naïve patients (from US label):</i> Fosamprenavir 1400 mg twice daily alone Fosamprenavir 1400 mg + ritonavir 200 mg, both once daily Fosamprenavir 1400 mg + ritonavir 100 mg, both once daily	<b>Oral suspension:</b> Should be taken without food and on an empty stomach	Administration of fosamprenavir oral suspension (1400 mg single dose) with a high fat meal (967 kcal, 67 g fat, 33 g protein, 58 g carbohydrate) decreased amprenavir C <sub>max</sub> and AUC by 46% and 28% when compared to the fasted state.
Indinavir	Indinavir 800 mg every 8 h alone or Indinavir 400 mg twice daily + ritonavir 100 mg twice daily	<b>Indinavir alone:</b> For optimal absorption, indinavir should be administered without food but with water 1 hour before or 2 hours after a meal. Alternatively, indinavir may be administered with other liquids (skim milk, juice, coffee, tea) or with a light meal.	Administration of indinavir with a meal high in calories, fat, and protein (784 kcal, 48.6 g fat, 31.3 g protein) decreased indinavir AUC and C <sub>max</sub> by 77% and 84% (n=10). Administration with lighter meals (e.g., a meal of dry toast with jelly, apple juice, and coffee with skim milk and sugar or a meal of corn flakes, skim milk and sugar) resulted in little or no change in AUC, C <sub>max</sub> or trough concentration.
		<b>Indinavir + ritonavir:</b> Can be taken with or without food	No significant difference in indinavir exposure was seen when indinavir/ritonavir (800/100 mg twice daily) was given with a low fat or a high-fat meal.
Lopinavir/ritonavir	400/100 mg twice daily 800/100 mg once daily	<b>Tablets:</b> Can be taken with or without food	Administration of a single 400/100 mg dose of Kaletra tablets with a high fat meal (872 kcal, 56% fat) was associated with no significant changes in C <sub>max</sub> and AUC when compared to fasted state.
		<b>Oral solution:</b> Should be taken with food	Administration of a single 400/100 mg dose of Kaletra oral solution with a moderate fat meal (500-682 kcal, ~25% from fat) increased lopinavir AUC and C <sub>max</sub> by 80% and 54%, relative to fasting. Administration with a high fat meal (872 kcal, 56% fat) increased lopinavir AUC and C <sub>max</sub> by 130% and 56%, relative to fasting conditions.
Ritonavir	(Dose depends on coadministered PI)	Should be taken with food	Administration ritonavir (100 mg single dose) with a moderate or high fat meal decreased ritonavir AUC and C <sub>max</sub> by 20-23% (tablets) or 23-49% (oral solution), relative to fasting conditions.
Saquinavir	Saquinavir 1000 mg twice daily + ritonavir 100 mg twice daily	Should be taken with food or up to 2 hours after a meal.	Administration of saquinavir/ritonavir (1000/100 mg twice daily) with a high fat meal increased saquinavir AUC, C <sub>max</sub> and C <sub>min</sub> by 338%, 345% and 377%, when compared to fasting conditions.
Tipranavir	Tipranavir 500 mg twice daily + ritonavir 200 mg twice daily	Should be taken with food	No clinically significant changes in tipranavir C <sub>max</sub> , C <sub>12</sub> and AUC were observed when tipranavir/ritonavir was administered under fed conditions (500-682 kcal, 23-25% from fat) compared to fasted conditions. However, food improves the tolerability of tipranavir/ritonavir.

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### Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)

Antiretroviral	Usual adult dose	Food requirements	Comments
<b>Doravirine</b>	100 mg once daily	Can be taken with or without food	Administration of a single doravirine tablet with a high-fat meal (1000 kcal, 50% fat) to healthy subjects increased doravirine AUC, C <sub>max</sub> and C <sub>24</sub> by 16%, 3% and 36%, relative to fasting conditions.
<b>Efavirenz</b>	600 mg once daily	Should be taken on an empty stomach	Administration of a single 600 mg efavirenz tablet with a high fat meal (~1000 kcal, ~50% fat) increased efavirenz AUC and C <sub>max</sub> by 28% and 79% respectively, when given with a high fat meal relative to fasted conditions. This may lead to an increase in the frequency of adverse reactions. Administration of a single 600 mg dose of efavirenz capsules with a high-fat and calorie meal (894 kcal, 54 g fat, 54% calories from fat) increased efavirenz AUC and C <sub>max</sub> by 22% and 39%, whereas a reduced-fat and normal calorie meal (440 kcal, 2 g fat, 4% calories from fat) increased efavirenz AUC and C <sub>max</sub> by 17% and 51% (all relative to the exposures under fasted conditions).
<b>Etravirine</b>	200 mg twice daily	Should be taken following a meal	Etravirine AUC decreased by ~50% when administered under fasting conditions, as compared to administration following a meal. The total caloric content of the various meals evaluated ranged from 345 kcal (17 grams fat) to 1160 kcal (70 grams fat).
<b>Nevirapine</b>	<i>[Lead in dose - 200 mg once daily for the first 14 days]</i> 200 mg twice daily (immediate release) 400 mg once daily (prolonged release)	Can be taken with or without food	Administration of nevirapine immediate release (200 mg) to 24 healthy adults (12 female, 12 male), with a high-fat breakfast (857 kcal, 50 g fat, 53% of calories from fat) had no effect on nevirapine AUC relative to that observed under fasting conditions. Administration of nevirapine prolonged-release with a high fat meal, decreased nevirapine AUC and C <sub>min</sub> by ~6% and 2% relative to when patients were dosed with immediate-release tablets. The difference is not considered clinically relevant. The difference in nevirapine pharmacokinetics observed when nevirapine prolonged-release tablets are dosed under fasted or fed conditions is not considered clinically relevant.
<b>Rilpivirine</b>	25 mg once daily	Must be taken with a meal	Rilpivirine exposure was ~40% lower in a fasted state, compared to a normal meal (533 kcal) or high-fat high-calorie meal (928 kcal). When rilpivirine was taken with only a protein-rich nutritional drink, exposures were 50% lower than when taken with a meal. Rilpivirine must be taken with a meal to obtain optimal absorption. Taking rilpivirine in a fasted state or with only a nutritional drink may result in decreased plasma concentrations and potentially reduced therapeutic effect.

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### Nucleoside/tide Reverse Transcriptase Inhibitors

Antiretroviral	Usual adult dose	Food requirements	Comments
<b>Abacavir</b>	300 mg twice daily or 600 mg once daily	Can be taken with or without food	Food delays absorption and decreases C <sub>max</sub> , but does not affect AUC.
<b>Didanosine</b>	<i>≥60kg:</i> 400 mg once daily or 200 mg twice daily  <i>&lt;60kg:</i> 250 mg once daily or 125 mg twice daily	Should be taken on an empty stomach, at least 2 hours before or 2 hours after food	Administration of didanosine gastro-resistant capsules with a high fat meal significantly decreased didanosine AUC (19%) and C <sub>max</sub> (46%). Co-administering with, 1 h before or 2 h after a light meal, resulted in a significant decrease in AUC (27%, 24% and 10% respectively) and C <sub>max</sub> (22%, 15% and 15% respectively) compared to fasting state.  In another study, administration of didanosine capsules 1.5, 2 and 3 hours prior to a light meal resulted in equivalent C <sub>max</sub> and AUC values compared to fasting conditions.
<b>Emtricitabine</b>	<i>Hard Capsules:</i> 200 mg once daily  <i>10 mg/ml Oral Solution:</i> 240 mg (24 ml) once daily	Can be taken with or without food	Administration of emtricitabine capsules with a high fat meal (~1000 kcal) had no effect on emtricitabine AUC and decreased C <sub>max</sub> by 29%.  Emtricitabine AUC and C <sub>max</sub> were unaffected when emtricitabine oral solution was administered with either a high-fat or low-fat meal.
<b>Lamivudine</b>	300 mg once daily or 150 mg twice daily	Can be taken with or without food	Co-administration of lamivudine with food delayed T <sub>max</sub> and decreased C <sub>max</sub> by 47%. However, the extent (based on the AUC) of lamivudine absorbed was not affected.
<b>Stavudine</b>	<i>≥60kg:</i> 40 mg twice daily  <i>&lt;60kg:</i> 30 mg twice daily	<i>European SmPC:</i> Ideally taken on an empty stomach, at least 1 hour before food If this is not possible, it may be taken with a light meal.  <i>US Prescribing Information:</i> Can be taken with or without food	Administration of stavudine (40 mg twice daily) with a standardised, high-fat meal had no effect on stavudine AUC, but lowered C <sub>max</sub> and prolonged T <sub>max</sub> , when compared with fasting conditions. The clinical significance of this is unknown.
<b>Tenofovir-DF</b>	245 mg once daily	<i>European SmPC:</i> Should be taken with food  <i>US Prescribing Information:</i> Can be taken with or without food	Administration of tenofovir-DF with a high fat meal (~700-1000 kcal, 40-50% fat) increased tenofovir AUC and C <sub>max</sub> by ~40% and ~14%.  Administration of tenofovir-DF with a light meal had no significant effect on tenofovir pharmacokinetics.
<b>Zidovudine</b>	250 mg twice daily or 300 mg twice daily	Can be taken with or without food	Zidovudine AUCs were similar when a single dose of zidovudine was administered with or without food.

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## Entry/Integrase Inhibitors

Antiretroviral	Usual adult dose	Food requirements	Comments																														
<b>Bictegravir</b>	50 mg once daily (as fixed dose combination with emtricitabine and tenofovir alafenamide)	Can be taken with or without food	Administration of bictegravir/emtricitabine/tenofovir alafenamide with a moderate fat (~600 kcal, 27% fat) or high fat meal (~800 kcal, 50% fat) increased in bictegravir AUC and Cmax by 24% and 13%, relative to fasting conditions. This modest change is not considered clinically meaningful.																														
<b>Dolutegravir</b>	<i>Patients without documented or suspected INSTI resistance:</i> 50 mg once daily (twice daily when taken with some medicines).  <i>Patients with INSTI resistance (documented or suspected):</i> 50 mg twice daily.	<i>In the absence of integrase class resistance:</i> Can be taken with or without food	Administration of dolutegravir with low, moderate, and high fat meals increased dolutegravir AUC by 33%, 41%, and 66%; increased Cmax by 46%, 52%, and 67%; prolonged Tmax to 3, 4, and 5 h (from 2 h under fasted conditions), respectively relative to fasting conditions.																														
		<i>In the presence of integrase class resistance (European SmPC):</i> Preferably taken with food to enhance exposure, particularly in patients with Q148 mutations.	The European product label suggests that these increases may be clinically relevant in the presence of certain integrase class resistance and recommends dolutegravir to be taken with food by patients infected with HIV with integrase class resistance.  The US product label states that dolutegravir can be taken with or without food in all patients.																														
<b>Elvitegravir</b>	150 mg once daily (as fixed dosed combination with cobicistat, emtricitabine, and tenofovir-DF or tenofovir alafenamide)	Should be taken with food	Administration of elvitegravir as a fixed-dose combination with food increased elvitegravir Cmax and AUC, relative to fasting conditions (see the FDC listing for full details).																														
<b>Ibalizumab-uiyk</b>	Loading dose: 2000 mg IV Maintenance dose: 800 mg IV every 2 weeks	Not applicable (IV administration)																															
<b>Maraviroc</b>	<i>With potent CYP3A inhibitors ± potent CYP3A inducers:</i> 150 mg twice daily  <i>Without potent CYP3A inhibitors or inducers:</i> 300 mg twice daily  <i>With potent CYP3A inducer but no potent CYP3A inhibitor:</i> 600 mg twice daily	Can be taken with or without food	Administration of a maraviroc tablet (300 mg) with a high fat breakfast decreased maraviroc Cmax and AUC by 33%. Administration of maraviroc oral solution (75 mg) with a high fat breakfast decreased maraviroc AUC by 73%. Studies with the tablets demonstrated a reduced food-effect at higher doses.  There were no food restrictions in adult studies (using tablet formulations) or in a paediatric study (using both tablet and oral solution formulations) and results did not indicate any relevant efficacy or safety concern related to either fed or fasted dosing conditions. Therefore, maraviroc tablets and oral solution can be taken with or without food.																														
<b>Raltegravir</b>	400 mg twice daily or 1200 mg once daily (if treatment naïve or virally suppressed on 400 mg twice daily)	Can be taken with or without food	Administration of raltegravir film-coated tablets with food had the following effects on raltegravir pharmacokinetics (relative to fasting): <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th></th> <th colspan="3">400 mg twice daily</th> <th colspan="2">1200 mg once daily</th> </tr> <tr> <th></th> <th>Low fat</th> <th>Moderate fat</th> <th>High fat</th> <th>Low fat</th> <th>High fat</th> </tr> </thead> <tbody> <tr> <td>AUC</td> <td>↓46%</td> <td>↑13%</td> <td>↑111%</td> <td>↓42%</td> <td>↑2%</td> </tr> <tr> <td>Cmax</td> <td>↓52%</td> <td>↑5%</td> <td>↑96%</td> <td>↓52%</td> <td>↓28%</td> </tr> <tr> <td>Cmin</td> <td>↓14%</td> <td>↑66%</td> <td>↑313%</td> <td>↓16%</td> <td>↓12%</td> </tr> </tbody> </table> Administration of raltegravir chewable tablets with a high fat meal decreased AUC and Cmax by 6% and 62%, and increased Cmin by 188%. The effect of food on oral suspension was not studied.  Food appears to increase pharmacokinetic variability relative to fasting.		400 mg twice daily			1200 mg once daily			Low fat	Moderate fat	High fat	Low fat	High fat	AUC	↓46%	↑13%	↑111%	↓42%	↑2%	Cmax	↓52%	↑5%	↑96%	↓52%	↓28%	Cmin	↓14%	↑66%	↑313%	↓16%	↓12%
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### Fixed Dose Combinations - PIs + NRTIs

Name	ARVs	Food requirements	Comments															
<b>Symtuza</b>	Darunavir/cobicistat + Emtricitabine Tenofovir alafenamide	Should be taken with food	Administration with a high fat meal (928 kcal; 504 kcal fat (56 g), 260 kcal carbohydrates, 164 kcal protein) had the following effects on the components of Symtuza (relative to fasting):  <table border="0"> <tr> <td></td> <td><i>Darunavir</i></td> <td><i>Cobicistat</i></td> <td><i>Emtricitabine</i></td> <td><i>Tenofovir alafenamide</i></td> </tr> <tr> <td>AUC</td> <td>↑52%</td> <td>↑41%</td> <td>↔</td> <td>↑12%</td> </tr> <tr> <td>Cmax</td> <td>↑82%</td> <td>↑30%</td> <td>↓21%</td> <td>↓45%</td> </tr> </table> The type of food does not affect exposure to Symtuza.		<i>Darunavir</i>	<i>Cobicistat</i>	<i>Emtricitabine</i>	<i>Tenofovir alafenamide</i>	AUC	↑52%	↑41%	↔	↑12%	Cmax	↑82%	↑30%	↓21%	↓45%
	<i>Darunavir</i>	<i>Cobicistat</i>	<i>Emtricitabine</i>	<i>Tenofovir alafenamide</i>														
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### Fixed Dose Combinations - NNRTIs + NRTIs

Name	ARVs	Food requirements	Comments																					
<b>Atripla</b>	Efavirenz + Emtricitabine Tenofovir-DF	Take on an empty stomach	Atripla has not been evaluated in the presence of food.  Atripla is recommended for administration on an empty stomach since food may increase efavirenz exposure and may lead to increased frequency of adverse reactions. Administration of efavirenz tablets with a high fat meal increased efavirenz AUC and Cmax by 28% and 79%, relative to fasting.  It is anticipated that tenofovir AUC will be ~30% lower following administration of Atripla on an empty stomach as compared to the individual component when taken with food. Administration of emtricitabine/tenofovir-DF with either a high fat or light meal had no effect on emtricitabine but increased tenofovir AUC and Cmax by 35% and 15%, relative to fasting.																					
<b>Delstrigo</b>	Doravirine + Lamivudine Tenofovir-DF	Can be taken with or without food	Administration of a single Delstrigo tablet with a high fat meal (~1000 kcal, 50% fat) had the following effects on the components of Delstrigo (relative to fasting):  <table border="0"> <tr> <td></td> <td><i>Doravirine</i></td> <td><i>Lamivudine</i></td> <td><i>Tenofovir-DF</i></td> </tr> <tr> <td>AUC</td> <td>↑10%</td> <td>↓7%</td> <td>↑27%</td> </tr> <tr> <td>Cmax</td> <td>↓5%</td> <td>↓19%</td> <td>↓12%</td> </tr> <tr> <td>C24</td> <td>↑26%</td> <td>ND</td> <td>ND</td> </tr> </table>		<i>Doravirine</i>	<i>Lamivudine</i>	<i>Tenofovir-DF</i>	AUC	↑10%	↓7%	↑27%	Cmax	↓5%	↓19%	↓12%	C24	↑26%	ND	ND					
	<i>Doravirine</i>	<i>Lamivudine</i>	<i>Tenofovir-DF</i>																					
AUC	↑10%	↓7%	↑27%																					
Cmax	↓5%	↓19%	↓12%																					
C24	↑26%	ND	ND																					
<b>Eviplera (Europe) Complera (US)</b>	Rilpivirine + Emtricitabine Tenofovir-DF	Must be taken with food	Administration with either a light meal (390 kcal, 12 g fat) or a standard meal (540 kcal, 21 g fat) increased exposures of rilpivirine and tenofovir relative to fasting conditions. Emtricitabine exposures were not affected by food.  <table border="0"> <tr> <td></td> <td colspan="2"><i>Light Meal</i></td> <td colspan="2"><i>Standard Meal</i></td> </tr> <tr> <td></td> <td><i>Rilpivirine</i></td> <td><i>Tenofovir-DF</i></td> <td><i>Rilpivirine</i></td> <td><i>Tenofovir-DF</i></td> </tr> <tr> <td>AUC</td> <td>↑9%</td> <td>↑28%</td> <td>↑16%</td> <td>↑38%</td> </tr> <tr> <td>Cmax</td> <td>↑34%</td> <td>↑12%</td> <td>↑26%</td> <td>↑32%</td> </tr> </table>		<i>Light Meal</i>		<i>Standard Meal</i>			<i>Rilpivirine</i>	<i>Tenofovir-DF</i>	<i>Rilpivirine</i>	<i>Tenofovir-DF</i>	AUC	↑9%	↑28%	↑16%	↑38%	Cmax	↑34%	↑12%	↑26%	↑32%	
	<i>Light Meal</i>		<i>Standard Meal</i>																					
	<i>Rilpivirine</i>	<i>Tenofovir-DF</i>	<i>Rilpivirine</i>	<i>Tenofovir-DF</i>																				
AUC	↑9%	↑28%	↑16%	↑38%																				
Cmax	↑34%	↑12%	↑26%	↑32%																				
<b>Odefsey</b>	Rilpivirine + Emtricitabine Tenofovir alafenamide	Must be taken with food	Administration of a single Odefsey tablet with either a moderate fat meal (~600 kcal, 27% fat) or a high fat meal (~800 kcal, 50% fat) had the following effects on the components of Odefsey (relative to fasting):  <table border="0"> <tr> <td></td> <td colspan="3"><i>Moderate Fat Meal</i></td> <td colspan="3"><i>High Fat Meal</i></td> </tr> <tr> <td></td> <td><i>Rilpivirine</i></td> <td><i>Emtricitabine</i></td> <td><i>Tenofovir alafenamide</i></td> <td><i>Rilpivirine</i></td> <td><i>Emtricitabine</i></td> <td><i>Tenofovir alafenamide</i></td> </tr> <tr> <td>AUC</td> <td>↑13%</td> <td>↓9%</td> <td>↑45%</td> <td>↑72%</td> <td>↓12%</td> <td>↑39%</td> </tr> </table>		<i>Moderate Fat Meal</i>			<i>High Fat Meal</i>				<i>Rilpivirine</i>	<i>Emtricitabine</i>	<i>Tenofovir alafenamide</i>	<i>Rilpivirine</i>	<i>Emtricitabine</i>	<i>Tenofovir alafenamide</i>	AUC	↑13%	↓9%	↑45%	↑72%	↓12%	↑39%
	<i>Moderate Fat Meal</i>			<i>High Fat Meal</i>																				
	<i>Rilpivirine</i>	<i>Emtricitabine</i>	<i>Tenofovir alafenamide</i>	<i>Rilpivirine</i>	<i>Emtricitabine</i>	<i>Tenofovir alafenamide</i>																		
AUC	↑13%	↓9%	↑45%	↑72%	↓12%	↑39%																		

Key: Can be taken with or without foodSpecific requirements for dosing relative to food intake

↑ Increase; ↓ decrease; ↔ no change; ND not determined

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# Food Considerations for Antiretrovirals

Revised July 2019

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## Fixed Dose Combinations – multiple NRTIs

Name	ARVs	Food requirements	Comments									
<b>Combivir</b>	Lamivudine Zidovudine	Can be taken with or without food	Lamivudine and zidovudine AUCs were similar when Combivir was administered with food and compared to fasting subjects, although the rates of absorption (C <sub>max</sub> , T <sub>max</sub> ) were slowed.									
<b>Descovy</b>	Emtricitabine Tenofovir alafenamide	Can be taken with or without food	Administration with a high fat meal (~800 kcal, 50% fat) had the following effects on the components of Descovy (relative to fasting):  <table style="margin-left: auto; margin-right: auto;"> <tr> <td></td> <td style="text-align: center;"><i>Emtricitabine</i></td> <td style="text-align: center;"><i>Tenofovir alafenamide</i></td> </tr> <tr> <td>AUC</td> <td style="text-align: center;">↓9%</td> <td style="text-align: center;">↑75%</td> </tr> <tr> <td>C<sub>max</sub></td> <td style="text-align: center;">↓26%</td> <td style="text-align: center;">↓15%</td> </tr> </table>		<i>Emtricitabine</i>	<i>Tenofovir alafenamide</i>	AUC	↓9%	↑75%	C <sub>max</sub>	↓26%	↓15%
	<i>Emtricitabine</i>	<i>Tenofovir alafenamide</i>										
AUC	↓9%	↑75%										
C <sub>max</sub>	↓26%	↓15%										
<b>Kivexa (Europe) Epzicom (US)</b>	Abacavir Lamivudine	Can be taken with or without food	No clinically significant food effect was observed. Administration of a single tablet of abacavir/lamivudine with a high-fat meal had no effect on abacavir AUC but decreased C <sub>max</sub> by ~24% relative to fasting conditions. There was no change in lamivudine AUC or C <sub>max</sub> .									
<b>Temixys</b>	Lamivudine Tenofovir-DF	Can be taken with or without food	<i>(No details of the effect of food on the fixed dosed combination are given in the product label.)</i>									
<b>Trizivir</b>	Abacavir Lamivudine Zidovudine	Can be taken with or without food	Administration of a single Trizivir tablet with a high fat meal decreased C <sub>max</sub> of abacavir, lamivudine and zidovudine by 32%, 18% and 28%, relative to fasting conditions. There was no effect on the AUCs of abacavir, lamivudine and zidovudine.									
<b>Truvada</b>	Emtricitabine Tenofovir-DF	<i>European SmPC:</i> It is preferable that Truvada is taken with food.	Administration of Truvada with either a light meal (373 kcal, 8 g fat) or a high fat meal (784 kcal, 49 g fat) increased tenofovir AUC and C <sub>max</sub> by ~35% and 15%, relative to fasting conditions. Emtricitabine AUC and C <sub>max</sub> were not affected by either a light meal or a high fat meal, relative to fasting conditions.									
		<i>US Prescribing Information:</i> Can be taken with or without food										

Key: Can be taken with or without foodSpecific requirements for dosing relative to food intake

↑ Increase; ↓ decrease; ↔ no change; ND not determined

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# Food Considerations for Antiretrovirals

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## Fixed Dose Combinations - Integrase Inhibitors + NRTIs

Name	ARVs	Food requirements	Comments																														
<b>Biktarvy</b>	Bictegravir + Emtricitabine Tenofovir alafenamide	Can be taken with or without food	Administration of Biktarvy with a high fat meal (800 kcal, 50% fat) had the following effects on pharmacokinetic parameters (relative to fasting):  <table> <tr> <td></td> <td><i>Bictegravir</i></td> <td><i>Emtricitabine</i></td> <td><i>Tenofovir alafenamide</i></td> </tr> <tr> <td>AUC</td> <td>↑24%</td> <td>↓4%</td> <td>↑63%</td> </tr> <tr> <td>Cmax</td> <td>↑13%</td> <td>↓14%</td> <td>↓8%</td> </tr> </table>		<i>Bictegravir</i>	<i>Emtricitabine</i>	<i>Tenofovir alafenamide</i>	AUC	↑24%	↓4%	↑63%	Cmax	↑13%	↓14%	↓8%																		
	<i>Bictegravir</i>	<i>Emtricitabine</i>	<i>Tenofovir alafenamide</i>																														
AUC	↑24%	↓4%	↑63%																														
Cmax	↑13%	↓14%	↓8%																														
<b>Dovato</b>	Dolutegravir + Lamivudine	Can be taken with or without food	Administration with a high fat meal (~900 kcal, 56% fat) had no clinically significant effect on the pharmacokinetics of either component of Dovato. When compared to fasting conditions, administration with food increased dolutegravir AUC by 33% and decreased lamivudine AUC by 9%.																														
<b>Genvoya</b>	Elvitegravir/cobicistat + Emtricitabine Tenofovir alafenamide	Should be taken with food	Administration of Genvoya with a light meal (~373 or 400 kcal, 20% fat) or a high fat meal (~800 kcal, 50% fat) had the following effects on pharmacokinetic parameters (relative to fasting):  <table> <tr> <td></td> <td colspan="2"><i>Light Meal</i></td> <td colspan="2"><i>High Fat Meal</i></td> </tr> <tr> <td></td> <td>AUC</td> <td>Cmax</td> <td>AUC</td> <td>Cmax</td> </tr> <tr> <td>Elvitegravir</td> <td>↑34%</td> <td>↑22%</td> <td>↑87%</td> <td>↑56%</td> </tr> <tr> <td>Cobicistat</td> <td>↑3%</td> <td>↔</td> <td>↓17%</td> <td>↓24%</td> </tr> <tr> <td>Emtricitabine</td> <td>↓5%</td> <td>↔</td> <td>↓4%</td> <td>↔</td> </tr> <tr> <td>Tenofovir alafenamide</td> <td>↑15%</td> <td>↔</td> <td>↑18%</td> <td>↔</td> </tr> </table>		<i>Light Meal</i>		<i>High Fat Meal</i>			AUC	Cmax	AUC	Cmax	Elvitegravir	↑34%	↑22%	↑87%	↑56%	Cobicistat	↑3%	↔	↓17%	↓24%	Emtricitabine	↓5%	↔	↓4%	↔	Tenofovir alafenamide	↑15%	↔	↑18%	↔
	<i>Light Meal</i>		<i>High Fat Meal</i>																														
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Elvitegravir	↑34%	↑22%	↑87%	↑56%																													
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Emtricitabine	↓5%	↔	↓4%	↔																													
Tenofovir alafenamide	↑15%	↔	↑18%	↔																													
<b>Juluca</b>	Dolutegravir + Rilpivirine	Must be taken with food to obtain optimal absorption of rilpivirine	Administration of Juluca with a moderate fat meal (~625 kcal, 32% fat) or a high fat meal (~900 kcal, 56% fat) had the following effects on pharmacokinetic parameters (relative to fasting):  <table> <tr> <td></td> <td colspan="2"><i>Moderate Fat Meal</i></td> <td colspan="2"><i>High Fat Meal</i></td> </tr> <tr> <td></td> <td>AUC</td> <td>Cmax</td> <td>AUC</td> <td>Cmax</td> </tr> <tr> <td>Dolutegravir</td> <td>↑87%</td> <td>↑75%</td> <td>↑87%</td> <td>↑75%</td> </tr> <tr> <td>Rilpivirine</td> <td>↑57%</td> <td>↑89%</td> <td>↑72%</td> <td>↑117%</td> </tr> </table> <p>Rilpivirine exposures were 50% lower when taken with only a protein-rich nutritional drink than with a meal. Taking Juluca in a fasted condition or with only a protein-rich nutritional drink may decrease rilpivirine concentrations, which could potentially reduce the therapeutic effect of Juluca.</p>		<i>Moderate Fat Meal</i>		<i>High Fat Meal</i>			AUC	Cmax	AUC	Cmax	Dolutegravir	↑87%	↑75%	↑87%	↑75%	Rilpivirine	↑57%	↑89%	↑72%	↑117%										
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Rilpivirine	↑57%	↑89%	↑72%	↑117%																													
<b>Stribild</b>	Elvitegravir/cobicistat + Emtricitabine Tenofovir-DF	Should be taken with food	Administration of Stribild with a light meal (~373 kcal, 20% fat) or a high fat meal (~800 kcal, 50% fat) had the following effects on pharmacokinetic parameters (relative to fasting):  <table> <tr> <td></td> <td colspan="2"><i>Light Meal</i></td> <td colspan="2"><i>High Fat Meal</i></td> </tr> <tr> <td></td> <td>AUC</td> <td>Cmax</td> <td>AUC</td> <td>Cmax</td> </tr> <tr> <td>Elvitegravir</td> <td>↑34%</td> <td>↑22%</td> <td>↑87%</td> <td>↑56%</td> </tr> <tr> <td>Cobicistat</td> <td>↑3%</td> <td>↔</td> <td>↓17%</td> <td>↓24%</td> </tr> <tr> <td>Emtricitabine</td> <td>↓5%</td> <td>↔</td> <td>↓4%</td> <td>↔</td> </tr> <tr> <td>Tenofovir-DF</td> <td>↑24%</td> <td>↑20%</td> <td>↑23%</td> <td>↔</td> </tr> </table>		<i>Light Meal</i>		<i>High Fat Meal</i>			AUC	Cmax	AUC	Cmax	Elvitegravir	↑34%	↑22%	↑87%	↑56%	Cobicistat	↑3%	↔	↓17%	↓24%	Emtricitabine	↓5%	↔	↓4%	↔	Tenofovir-DF	↑24%	↑20%	↑23%	↔
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Emtricitabine	↓5%	↔	↓4%	↔																													
Tenofovir-DF	↑24%	↑20%	↑23%	↔																													
<b>Triumeq</b>	Dolutegravir + Abacavir Lamivudine	Can be taken with or without food	Administration of Triumeq with a high fat meal (869 kcal, 53% fat) had the following effects on pharmacokinetic parameters (relative to fasting):  <table> <tr> <td></td> <td><i>Dolutegravir</i></td> <td><i>Abacavir</i></td> <td><i>Lamivudine</i></td> </tr> <tr> <td>AUC</td> <td>↑48%</td> <td>↔</td> <td>↔</td> </tr> <tr> <td>Cmax</td> <td>↑37%</td> <td>↓23%</td> <td>↔</td> </tr> </table>		<i>Dolutegravir</i>	<i>Abacavir</i>	<i>Lamivudine</i>	AUC	↑48%	↔	↔	Cmax	↑37%	↓23%	↔																		
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