

## LIPID-LOWERING AGENTS

Drug	Dose	Metabolism	Efficacy	Onset	Interactions	Side Effects	Cost
<b>FIBRIC ACID DERIVATIVES</b>							
bezafibrate Bezalip® (Roche)	400 mg SR once daily or 200 mg tid with meals	Cirenal (50% unchanged, 20% glucuronides) - hydroxylation and glucuronidation	↓ 20% total cholesterol, ↓ (50%) TG, ↓ 20% LDL, variable ↑ 20% HDL	Decrease in TG within 1- 2 months, increase HDL in 3-6 months	Decrease dose in renal failure; ritonavir & nelfinavir may ↑ clearance via GT induction	GI disturbances, rash, headache, insomnia, myositis, elevated CPK	usual: \$1.60/day (ODB) \$1.60/400 mg \$0.6183/200 mg
clofibrate Atromid-S® (Ayerst)	1 g bid with food	Esterase to CPIB (active form), then GT	↓ 20% total cholesterol, ↓ 45% TG, ↓ variable LDL, variable ↑ HDL	Effect within 2-5 days, max response in 21 days	Caution with ritonavir; ritonavir & nelfinavir may ↑ clearance via GT induction	GI disturbances, potential carcinogenicity, rash, headache, myositis, elevated CPK	not covered by ODB
fenofibrate Lipidil®, Lipidil Micro® (Fournier)	200 mg daily with food (max. 300 mg/day)	Prodrug, - hydrolyzed to fenofibric acid and GT; Cirenal	↓ 30% total cholesterol, ↓↓ 50%TG, ↓ 20% LDL, ↑ 15% HDL	Effect within 6-8 weeks	Decrease dose in renal failure; ritonavir & nelfinavir may ↑ clearance via GT induction	GI disturbances, rash, headache, myositis, elevated CPK	usual: \$1.21/day (ODB) \$0.4325/100 mg \$1.21/200 mg
gemfibrozil Lopid® (Parke Davis)	600 mg BID (max. 1200 mg/day)	30-50% GT, CYP (?)	↓ 10% total cholesterol, ↓ 45% TG, ↓ variable LDL, ↑ 15% HDL	Max. response in 4weeks	Ritonavir & nelfinavir may ↑ clearance via GT induction.  In a healthy volunteer study, subjects received single dose gemfibrozil 600 mg before and after 14 days of <b>LPV 400/rtv 100 mg BID</b> . In the presence of steady-	GI distress and rash	usual: \$1.19/day (ODB) \$0.2964/300 mg

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					state LPVr, gemfibrozil AUC was ↓ 41%. <sup>1</sup>		
<b>HMG-COA-REDUCTASE INHIBITORS</b>							
atorvastatin Lipitor® (Parke Davis)	10 mg qhs, max. 80 mg/day; make dose changes q4 weeks	CYP3A4	↓ 28-40% total cholesterol, ↓ 13-32% TG, ↓ 38-51% LDL, ↑ 5-6% HDL	Effect within 2 weeks, maximum response at 2-4 weeks	Pharmacokinetic studies in HIV-negative subjects: a) <b>saquinavir</b> 400 mg/ritonavir 400 mg BID plus 40 mg atorvastatin resulted in a 4.5-fold ↑ AUC atorvastatin. <sup>2</sup> b) <b>nelfinavir</b> 1250 mg BID plus 10 mg atorvastatin resulted in 74% ↑ AUC atorvastatin <sup>3</sup> c) <b>lopinavir</b> 400 mg/ritonavir 100 mg BID plus 20 mg atorvastatin resulted in 5.9-fold ↑ AUC <sup>2, 4</sup> d) <b>fosamprenavir</b> 1400 mg BID or fosamprenavir 700 mg/ritonavir 100 mg BID plus atorvastatin 10 mg resulted in significant ↑ in atorvastatin Cmax (404% and 284%, respectively) and	Abdominal cramps, nausea, myalgia, thrombocytopenia, ↑CPK, ↑LFTs	usual: \$2.00/day (ODB) \$1.60/10 mg \$2.00/20 mg \$2.15/40 mg

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					<p>AUC (230% and 253%, respectively); APV levels were not affected.<sup>5</sup></p> <p>e) <b>tipranavir</b> 500 mg/ ritonavir 200 mg BID led to 9-fold ↑ atorvastatin AUC. Recommend starting with atorvastatin 10 mg QD and titrating upwards in presence of TPV/r.<sup>6</sup></p> <p>f) Combination of atorvastatin 10 mg daily plus <b>darunavir 300/ritonavir</b> 100 mg BID led to 15% ↓ atorvastatin AUC vs. atorvastatin 40 mg QD alone. Recommend starting with atorvastatin 10 mg QD and titrating upwards in presence of darunavir/ritonavir.</p> <p>Use cautiously (e.g., start at 10 mg/day)</p>		

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					<p>with PIs and delavirdine.<sup>7</sup></p> <p>With <b>efavirenz</b> 600 mg/d and atorvastatin 10 mg/d:</p> <ul style="list-style-type: none"> <li>- significant ↓ <b>atorvastatin</b> AUC by 43% (total active atorvastatin exposure ↓ 34%); EFV concentrations not affected.</li> </ul> <p>Patients on combination should be closely monitored for anti-lipid activity; statin dose may need to be titrated.<sup>8</sup></p> <p>In healthy volunteers, atorvastatin 40 mg QD plus <b>etravirine</b> 800 mg BID (old formulation) led to 37% ↓ AUC of atorvastatin and 27% ↑ AUC atorvastatin active metabolite. Etravirine exposures were not affected. Combination may be coadministered.<sup>9</sup></p> <p>In healthy volunteers, atorvastatin 40 mg QD</p>		

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					plus <b>rilpivirine 150 mg QD</b> did not lead to significant alterations in plasma exposures of either rilpivirine or atorvastatin. A modest increase in exposure to atorvastatin hydroxylated metabolites (via mild induction of CYP3A activity by rilpivirine) resulted in an increase in the total lipid-lowering activity of atorvastatin during rilpivirine coadministration; this was considered clinically relevant. Combination may be coadministered without dose adjustment. <sup>10</sup>		
fluvastatin Lescol® (Novartis)	20 mg qhs (max. 40 mg qhs or 20 mg BID)	extensive 1 <sup>st</sup> -pass; CYP2C9 >>3A4 (minor) ; weak inhibitor of 2C9	↓ 13-23% total cholesterol, ↓ 5-15% TG, ↓ 17-34% LDL, ↑ 1-7% HDL	maximum response within 4 weeks	May be less likely to interact with PIs; caution with ritonavir (induces 2C9 but inhibits 3A).	Same as above - dyspepsia and lupus-like syndrome	(ODB) \$0.75/20 mg \$1.05/40 mg
lovastatin Mevacor® (Merck)	10-20 mg cc (max. 40 mg BID or 80 mg cc)	hydrolysis to active form, CYP3A4, also 2D6, 2C9	↓ 21-36% total cholesterol, ↓ 12-13% TG, ↓ 29-48%	Effect within 3 days, maximum response at 4-6 weeks	Elevated liver function tests, myalgias reported with concomitant use of lovastatin and PI	Same as atorvastatin -lupus-like syndrome and ↑LFTS 3x normal	(ODB) \$1.2985/20 mg \$2.3951/40 mg

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			LDL, ↑ 7-8% HDL		therapy. <sup>11</sup> Avoid with all PIs (esp. ritonavir), delavirdine. <sup>7</sup>		
pitavastatin		Minimal CYP450			In healthy volunteers, administration of pitavastatin 4 mg daily in the presence of steady-state <b>lopinavir/ritonavir 400/100 mg BID</b> did not result in clinically significant changes in pharmacokinetic exposures of either drug. <sup>12</sup>		
pravastatin Pravachol® (Squibb)	10-20 mg qhs (max. 40 mg qhs)	40-54% Clrenal; >50% metab. by CYP3A(?)	↓ 13-24% total cholesterol, ↓ 10-15% TG, ↓ 19-34% LDL, ↑ 3-10% HDL	Effect within 3 days, maximum response at 4-6 weeks	Pharmacokinetic studies in HIV-negative subjects: a) <b>saquinavir 400 mg/ritonavir 400 mg BID</b> plus 40 mg pravastatin resulted in a 35% ↓ AUC of pravastatin. <sup>2</sup> b) <b>lopinavir 400 mg/ritonavir 100 mg BID</b> + pravastatin 20 mg: 30% ↑ pravastatin AUC <sup>4</sup> c) <b>darunavir 600 mg/ rtv 100 mg BID</b> plus single-dose pravastatin 40 mg led to 81% ↑ pravastatin AUC. When co-	Same as atorvastatin	(ODB) \$1.0593/10 mg \$1.2495/20 mg \$1.505/40 mg

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					<p>administration is required, the lowest possible pravastatin dose should be used.<sup>13</sup></p> <p>d) <b>Nelfinavir 1250 mg BID</b> + pravastatin 40 mg QD: 46.5% ↓ pravastatin AUC. Patients on combination should be closely monitored for anti-lipid activity; pravastatin dose may need to be titrated.<sup>14</sup></p> <p>Addition of pravastatin 40 mg daily to either <b>indinavir, saquinavir, or ritonavir</b>-containing regimens (n=15) did not result in any significant changes to PI concentrations.<sup>15</sup> Pravastatin may be administered without dosage adjustment.</p> <p>With <b>efavirenz</b> 600 mg/d and pravastatin 40 mg/d, <b>pravastatin</b> AUC ↓ 40%; EFV concentrations not</p>		

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					<p>affected. Patients on combination should be closely monitored for anti-lipid activity; statin dose may need to be titrated.<sup>8</sup></p> <p>In healthy adults who received pravastatin 40 mg QD plus <b>raltegravir</b> 400 mg BID for 4 days, pravastatin exposures were not significantly affected in the presence of raltegravir. Raltegravir AUC ↑ 13%, Cmax ↑ 31% and C12 ↓ 41% when coadministered with pravastatin; however, since raltegravir efficacy is better correlated with AUC, this interaction is not likely to be clinically significant, and no dose adjustments are required.<sup>16</sup></p>		
rosuvastatin Crestor® (Astra Zeneca)	5-20 mg once daily (max. 40 mg daily). May be given with/ without food	Minimal (10%) hepatic metabolism, mostly through CYP2C9, 2C19. Mostly excreted in bile.	28-30%↓ total cholesterol, ↓ 40-58%↓ LDL, 12-15% ↓ TG, 7-12% ↑ HDL	Within 2 weeks, maximal response at 6-12 weeks.	Prospective study with 6 healthy adult volunteers of <b>ATV/r</b> <b>300mg/100mg daily</b> for 7 days and rosuvastatin 10mg single dose led to	Headache, asthenia, upper respiratory infections, gastrointestinal symptoms, and myalgia have been	(ODB) \$1.36/10 mg \$1.70/20 mg \$1.99/40 mg

Drug	Dose	Metabolism	Efficacy	Onset	Interactions	Side Effects	Cost
	at any time of day.				<p>213% ↑ rosuvastatin AUC, 600% ↑ Cmax vs. rosuvastatin alone. Rosuvastatin-lactone AUC ↑ 61%, no change in N-desmethyl rosuvastatin levels. Authors suggest maximum 10-20 mg/day rosuvastatin be used when given with ATV/r. May wish to titrate rosuvastatin dose based on lipid response. Monitor patient closely for ADRs.<sup>17</sup></p> <p>In healthy volunteers who received rosuvastatin 10 mg daily alone or with <b>darunavir 600/100 mg BID</b> for 7 days, mean rosuvastatin AUC ↑ 48% and Cmax ↑ 144% in the presence of darunavir/ritonavir. Darunavir kinetics were not significantly affected by rosuvastatin. Lipid-lowering effects of rosuvastatin were not significantly altered in</p>	reported; myopathy has occurred rarely	

Drug	Dose	Metabolism	Efficacy	Onset	Interactions	Side Effects	Cost
					<p>the presence of darunavir/ritonavir.<sup>18</sup></p> <p>In a prospective study of healthy volunteers, <b>FPV/r 700mg/100mg BID</b> for 7 days did not affect the AUC or Cmax of rosuvastatin 10mg (single dose) or N-desmethyl Rosuvastatin levels (metabolite). FPV/r ↑ rosuvastatin-lactone AUC (metabolite) by 76%. Based on PK data, no dose adjustments required when combination is used.<sup>17</sup></p> <p>In a prospective cohort of HIV-positive subjects (n=14) on <b>lopinavir/r</b> regimens, LPV Cmin were not changed during 12 weeks of rosuvastatin therapy;<sup>19</sup> however, rosuvastatin concentrations were 1.5-2-fold higher compared to historical data.<sup>20</sup></p> <p>In an open-label, 3-phase pharmacokinetic study</p>		

Drug	Dose	Metabolism	Efficacy	Onset	Interactions	Side Effects	Cost
					<p>in healthy volunteers, the combination of <b>rosuvastatin 20 mg/day plus LPV/r 400/100 mg BID</b> for 7 days led to a 2.1-fold ↑ AUC and 4.7-fold ↑ Cmax of rosuvastatin, compared to rosuvastatin alone (p&lt;0.0001). LPV levels were not changed in the presence of rosuvastatin.<sup>21</sup></p> <p>Use combination with caution until further data available.</p> <p>In 16 healthy volunteers, <b>tipranavir 500/ritonavir 200 mg BID</b> plus single dose rosuvastatin 10 mg led to 37% ↑ AUC and 123% ↑ Cmax of rosuvastatin; TPV and RTV levels were not changed in the presence of rosuvastatin. Use lowest dose of rosuvastatin (5 mg/day) and titrate slowly to treatment response.<sup>6</sup></p>		

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simvastatin Zocor® (Merck Frosst)	5-10 mg before supper or hs (max. 20 mg BID or 40 mg before supper or hs)	hydrolysis to active form, CYP3A; also CYP2D6, 2C9	↓ 21-30% total cholesterol, ↓ 12-15% TG, ↓ 28-39% LDL, ↑ 7-10% HDL	Effect within 3 days, maximum response at 4-6 weeks	Pharmacokinetic studies in HIV- negative subjects: a) saquinavir 400 mg/ritonavir 400 mg BID plus 40 mg simvastatin resulted in a 31.6 fold ↑ AUC simvastatin. <sup>2</sup> b) nelfinavir 1250 mg BID plus 20 mg simvastatin resulted in 506% ↑ AUC simvastatin <sup>3</sup>  Avoid concomitant use with all protease inhibitors and delavirdine. <sup>7</sup>  With <b>efavirenz</b> 600 mg/d and simvastatin 40 mg/d: - significant ↓ <b>simvastatin</b> AUC by 58% (active HMG-CoA reductase inhibitory activity ↓ 60%); EFV concentrations not affected.  Patients on combination should be closely monitored for anti-lipid activity; statin dose may need to be	Same as atorvastatin - lupus-like syndrome and thrombocytopenic purpura	(ODB) \$0.90/5 mg \$1.78/10 mg \$2.20/20 mg \$2.20/40 mg \$2.20/80 mg

Drug	Dose	Metabolism	Efficacy	Onset	Interactions	Side Effects	Cost
					titrated. <sup>8</sup>		
<b>CHOLESTEROL ABSORPTION INHIBITORS</b>							
Ezetimibe (Ezetrol®)	10 mg once daily +/- food	Glucuronidated in gut wall to active metabolite	Monotherapy: 18%↓ LDL, 5% ↓ TG, 4%↑ HDL; Combined with atorvastatin: 54.5%↓ LDL, 33%↓ TG, 7%↑ HDL (all parameters sig. > vs. atorvastatin alone)	Onset within 1 week, peak ↓ LDL within 2-4 weeks	<p><b>Fibrates:</b> ezetimibe concentrations ↑ 1.7-fold with gemfibrozil, ↑ 1.5-fold with fenofibrate; fibrates ↑ cholesterol excretion into bile, leading to ↑ risk cholelithiasis. Avoid co-administration, may need to ↑ ezetimibe dose.</p> <p><b>Cyclosporine:</b> 12-fold ↑ ezetimibe levels reported in renal transplant patient, mechanism unknown. Co-administer with caution.</p> <p><b>Lopinavir/rtv:</b> Ezetimibe 10 mg QD for 12-18 weeks did not affect steady-state kinetics of lopinavir/ritonavir in HIV-infected subjects.<sup>22, 23</sup></p> <p><b>Raltegravir:</b> Steady-state kinetics of raltegravir 400 mg BID were not affected by ezetimibe 10 mg QD for 10 days in healthy subjects.<sup>24</sup></p>	GI: dyspepsia, diarrhea	(ODB): \$1.58/10 mg

Drug	Dose	Metabolism	Efficacy	Onset	Interactions	Side Effects	Cost
<b>BILE ACID SEQUESTRANTS</b>							
cholestyramine Questran® (Bristol)	4 g 30-60 min before 1-2 main meals (max. 8g before 2-3 meals)	not metabolized	↓ (15-30%) LDL; may ↑ (15-25%) TG (via compensatory ↑ hepatic synthesis of VLDL?)	Effect within 24-48 hrs and cont'd up to 12 months	May ↓ absorption of other drugs (e.g., thiazides, propranolol, thyroxine, warfarin, cardiac glycosides, fat-soluble vitamins); take other drugs 1 hr before or 2-4 hrs after bile acid resin	GI: dyspepsia, N/V, abdominal discomfort, bloating, constipation; no systemic s/e	(ODB) \$19.92/42 doses \$0.6407/pouch
colestipol HCl Colestid® (Pharmacia & Upjohn)	5 g 30-60 min before 1-2 main meals (max. 10 g before 2-3 meals)	not metabolized	↓ LDL; may ↑ TG (via compensatory ↑ hepatic synthesis of VLDL?)	Effect within 24-48 hrs, maximum response at 1 month	as above	GI: dyspepsia, N/V, abdominal discomfort, bloating, constipation; no systemic side effects	(ODB) \$0.8183/5g \$0.8183/7.5 g \$46.00/60 doses
<b>OTHER</b>							
niacin/ nicotinic acid/vitamin B3	250-500 mg BID after meals (max. 1-2 g BID-TID pc); use immediate-release form to ↓ risk liver toxicity	Metabolized to active metabolite niacinamide	↓ (20-35%) LDL, ↓(20-40%) TG, ↑ (10-20%) HDL, ↓ lipoprotein a	Effect within 3-5 weeks	Increased effect of insulin and oral hypoglycemics -increased myopathy when administered with statins or fibric acid derivatives. Potential for overlapping toxicities with PIs, especially ritonavir.	flushing, pruritus, N/ GI discomfort, gastritis, blurred vision; alters serum glucose, uric acid levels; Long term: hyperuricemia, hepatotoxicity, PUD; rhabdomyolysis (in combination with HMG-CoA reductase inhibitors)	\$0.0295/100 mg

Please note: This chart summarizes some of the major drug interactions identified to date, based on current available data; other drug interactions may exist. Please use caution whenever adding/modifying therapy. The information in this table is intended for use by experienced physicians and pharmacists. It is not intended to replace sound professional judgment in individual situations, and should be used in conjunction with other reliable sources of information. Due to the rapidly changing nature of information about HIV treatment and therapies, users are advised to recheck the information contained herein with the original source before applying it to patient care.

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