<table>
<thead>
<tr>
<th>DRUG</th>
<th>DOSAGE</th>
<th>SIDE EFFECTS</th>
<th>SPECIAL INSTRUCTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abacavir (ABC)</td>
<td></td>
<td></td>
<td>Can be given without regard to food. Patients need to be instructed about how to recognize and respond to potentially fatal hypersensitivity reactions. Patients should not interrupt therapy without consulting their physician. Reduce dose in patients with hepatic impairment. Alcohol increases abacavir concentrations by 41%. Patients should be tested for HLAb*5701 allele prior to initiating therapy to predict risk of ABC hypersensitivity reaction. Patients who are positive should not be given ABC and potential for ABC allergy should be noted in their medical records. Trizivir and Epzicom should not be used in patients with CrCl &lt; 50 mL/min, patients on dialysis, or patients with impaired hepatic function. In clinically stable patients receiving ABC with undetectable viral loads and stable CD4 counts for ≥ 24 weeks, switch to once daily dosing (160-200 mg/kg/day) may be considered.</td>
</tr>
<tr>
<td>Class: NRTI</td>
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<tr>
<td>ZIAGEN, generic</td>
<td></td>
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<tr>
<td>Preparations: Tablets: 300 mg scored Oral Solution: 20 mg/ml Tablets in combination with zidovudine, dolutegravir, and lamivudine: TRIZIVIR, generic- 300 mg zidovudine + 150 mg lamivudine + 300 mg abacavir EPZICOM-300 mg lamivudine + 150 mg abacavir + 600 mg abacavir TRIUMEQ- 50 mg dolutegravir + 600 mg abacavir + 300 mg lamivudine</td>
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<tr>
<td>ZIAGEN</td>
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<tr>
<td>Epzicom</td>
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<tr>
<td>Trizivir</td>
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<td></td>
<td></td>
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<tr>
<td>Adult (≥18 years): 1 tablet once daily</td>
<td></td>
<td></td>
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<tr>
<td>Adult (16 years): 300 mg twice daily</td>
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<tr>
<td>Adult (2-16 years): 150 mg twice daily</td>
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<tr>
<td>Neonatal/Infant dose: Not approved for use in infants &lt; 3 months Pediatric (age ≥ 3 months): 8 mg/kg (max. 300 mg) twice daily or weight band dosing using scored tablets:</td>
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<tr>
<td>≥20 to &lt; 25 kg: 150 mg in am, 300 mg in pm</td>
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<tr>
<td>≥25 kg: 300 mg twice daily</td>
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<tr>
<td>Adult (≥18 years): 1 tablet twice daily</td>
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<tr>
<td>DPV</td>
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<tr>
<td>Epzicom</td>
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<tr>
<td>Trizivir</td>
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<td></td>
<td></td>
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<tr>
<td>Adult (≥18 years): 1 tablet once daily</td>
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<tr>
<td>Dolutegravir, and lamivudine:</td>
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<tr>
<td>Trizivir, generic- 300 mg zidovudine + 150 mg lamivudine + 300 mg abacavir EPZICOM-300 mg lamivudine + 150 mg abacavir + 600 mg abacavir TRIUMEQ- 50 mg dolutegravir + 600 mg abacavir + 300 mg lamivudine</td>
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<tr>
<td>Atazanavir (ATV)</td>
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<tr>
<td>Class: PI</td>
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<tr>
<td>REYATAZ</td>
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<tr>
<td>Capsules: 150 mg, 200 mg, and 300 mg Oral Powder 50 mg Packet: Oral powder is not interchangeable with capsule formulation. Tablets in combination with cobicistat: EVOTAZ- 300 mg atazanavir + 150 mg cobicistat</td>
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<tr>
<td>Neonatal/Infant dose: Not approved for use in neonates/infants. Should not be given to infants &lt;3 months of age due to risk of kernicterus. Pediatric Dose of Oral Powder in patients ≥ 10kg and &lt; 25kg (limited data on young children using oral powder):</td>
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<tr>
<td>10 to ≤ 15kg: 200 mg (4 packets) + RTV 80 mg, both once daily with food.</td>
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<tr>
<td>15 to &lt; 25kg: 250 mg (5 packets) + RTV 80 mg, both once daily with food.</td>
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<tr>
<td>Pediatric Dose (6&lt;18 years):</td>
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<tr>
<td>15 to &lt; 20 kg: ATV 150 mg + RTV 100 mg, both given once daily with food.</td>
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<tr>
<td>20 to &lt; 40 kg*: ATV 200 mg + RTV 100 mg, both given once daily with food. (Some experts recommend increasing to ATV 300 mg + RTV 100mg at ≥ 35 kg)</td>
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<tr>
<td>200 kg: ATV 300 mg + RTV 100 mg, both given once daily with food.</td>
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<tr>
<td>Neonatal/Infant dose: Not approved for use in infants &lt; 3 months of age due to risk of kernicterus. Pediatric (age ≥ 3 months): 8 mg/kg (max. 300 mg) twice daily or weight band dosing using scored tablets:</td>
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<td>≥20 to &lt; 25 kg: 150 mg in am, 300 mg in pm</td>
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<tr>
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<tr>
<td>Adult (≥18 years): 1 tablet twice daily</td>
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<tr>
<td>Adult (16 years): 300 mg twice daily or 600 mg once daily</td>
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<tr>
<td>TRIZIVIR (Adolescent weight ≥ 40 kg) Adult dose: One tablet twice daily.</td>
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<tr>
<td>EPZICOM (adolescent ≥ 16 years/adult dose): One tablet once daily.</td>
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<tr>
<td>TRIUMEQ (adult ≥ 18 years): One tablet once daily</td>
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</tr>
<tr>
<td>Atazanavir (ATV)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class: PI</td>
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<td>Capsules: 150 mg, 200 mg, and 300 mg Oral Powder 50 mg Packet: Oral powder is not interchangeable with capsule formulation. Tablets in combination with cobicistat: EVOTAZ- 300 mg atazanavir + 150 mg cobicistat</td>
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<tr>
<td>10 to ≤ 15kg: 200 mg (4 packets) + RTV 80 mg, both given once daily with food.</td>
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<tr>
<td>15 to &lt; 25kg: 250 mg (5 packets) + RTV 80 mg, both once daily with food.</td>
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<td></td>
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<tr>
<td>Pediatric Dose (6&lt;18 years):</td>
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<tr>
<td>15 to &lt; 20 kg: ATV 150 mg + RTV 100 mg, both given once daily with food.</td>
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<tr>
<td>Note: Dosing ATV with RTV is preferred for all children and adolescents regardless of age. However if unboosted ATV is used in children ≥ 13 years, higher doses than those used in adults may be required to achieve target drug levels. Therapeutic drug monitoring may be beneficial to ensure adequate ATV concentrations are achieved. Only boosted ATV should be used in patients who are treatment experienced. Adult Dose (≥ 18 years):</td>
<td></td>
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<tr>
<td>Antiretroviral-naive: ATV 400 mg (two 200 mg capsules) once daily with food or ATV 300 mg + RTV 100 mg once daily with food.</td>
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<tr>
<td>Antiretroviral-experienced: ATV 300 mg + RTV 100 mg once daily with food.</td>
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<tr>
<td>Combination Therapies (adults): Only boosted ATV with RTV should be used with EFV or TDF ATV plus EFV (therapy naive adults only): 400 mg ATV + 100 mg RTV + 600 mg EFV once daily but at separate times. ATV/RTV taken with food while EFV taken on an empty stomach.</td>
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<tr>
<td>More common: Asymptomatic elevations in indirect bilirubin (30%), jaundice (10%), headache, fever, arthralgias, depression, insomnia, dizziness, nausea, vomiting, diarrhea, and paresthesias. Less common: Nephrolithiasis, Prolongation of PR interval of EKG, First or second degree AV block, Skin rashes, including Stevens-Johnson syndrome. Rare: New onset diabetes mellitus, hyperglycemia, elevations in transaminases, Hepatotoxicity (patients with hepatitis B or C at increased risk), ATV/r may be associated with lipid abnormalities.</td>
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<tr>
<td>Many potential drug interactions as with other protease inhibitors. ATV is an inhibitor of CYP3A, UGT1A1 and CY2C8 (weak). CYP3A4 substrate. NVP and ETR should not be coadministered to patients receiving ATV. EFV should not be coadministered with ATV in treatment-experienced patients. Should be administered with food to enhance absorption. Powder must be given with ritonavir. Oral powder and capsule formulation are not interchangeable, Bioavailability is higher with the capsules than the oral powder. Do not open capsules. Use with caution in patients with pre-existing cardiac conduction disorders or with other drugs known to prolong the PR interval. Dosing of ATV in patients with hepatic impairment: ATV should be used with caution in patients with mild to moderate hepatic impairment. Consult prescribing information for adjustment of dosage in patients with moderate impairment. ATV should not be used in patients with severe hepatic impairment. ATV/r is not recommended in patients with any degree of hepatic impairment. Dosing of ATV in patients with renal impairment: No dose adjustment is required for patients with renal impairment. ATV should not be given to treatment-experienced patients with end stage renal disease on dialysis. Patients with HBV or HCV infections and those with marked elevations in transaminases prior to treatment are at increased risk of elevated transaminases or hepatic failure.</td>
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<tr>
<td>ATV plus TDF (adults): 300 mg ATV + 100mg RTV + 300 mg TDF once daily with food.</td>
<td>ATV absorption is dependent on low gastric pH and when administered with medications that alter gastric pH, special dosing information is required. Limited data on the use of oral powder, especially in the youngest patients. Oral powder must be taken with ritonavir and food and should not be used in children &lt; 10kg or &gt; 25 kg. Oral powder must be mixed with food or beverage for administration and ritonavir must be given immediately afterwards. Oral powder contains phenylalanine, which can be harmful in patients with phenylketonuria. Mixing oral powder: Preferable to mix with soft food. Mix packets with at least one tablespoon of food. Repeat with additional 15 mLs to drink residual mixture. Antacids: Antacids and buffered medications (including buffered ddI formulations) decrease ATV concentrations if administered at the same time; ATV should be administered 2 hours before or 1 hour after these medications. ATV solubility decreases as pH increases. Consult prescribing information if co-administered with an H-2 receptor antagonist or proton-pump inhibitor. Both of these classes of agents substantially decrease ATV plasma concentrations and therefore therapeutic response. PPI are not recommended in treatment-experienced patients on ATV. H2-Receptor Antagonists (unboosted ATV in treatment-naive patients): H2-receptor antagonists are expected to decrease ATV concentrations and interfere with absorption. ATV 400 mg should be administered at least 2 hours before or at least 10 hours after a dose of the H2-receptor antagonist (no single dose should exceed a dose comparable to famotidine 20 mg and total daily dose should not exceed a dose comparable to famotidine 40 mg). H2-Receptor Antagonists (boosted ATV in treatment-naive or experienced patients): H2-receptor antagonists are expected to decrease ATV concentrations and interfere with absorption. Dose recommendations for H2-receptor antagonists are either a ≤ 40 mg dose equivalent of famotidine twice daily (treatment-naive patients) or a ≤ 20 mg dose equivalent of famotidine twice daily (treatment-experienced patients). Dose: 300 mg ATV + 100 mg RTV should be administered simultaneously with and/or ≥ 10 hrs after the dose of H2-receptor antagonist. H2-Receptor Antagonists (boosted ATV with tenofovir): In treatment-experienced patients, if TDF is used with H2-</td>
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<tr>
<td>ATV plus Maraviroc (adults): 300 mg ATV + 100 mg RTV once daily with food + 150 mg MVC twice daily.</td>
<td>Pregnant Women: Only boosted ATV should be used in pregnant women. Treatment-experienced women during the second or third trimester on H2RA or TDF should be on increased dose of 400 mg ATV + 100 mg RTV once daily with food. ATV/r is not recommended in treatment-experienced pregnant women on H2RA + TDF. EVOTAZ (adult ≥ 18 years): One tablet once daily with food.</td>
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</tbody>
</table>

**Pregnant Women:** Only boosted ATV should be used in pregnant women. Treatment-experienced women during the second or third trimester on H2RA or TDF should be on increased dose of 400 mg ATV + 100 mg RTV once daily with food. ATV/r is not recommended in treatment-experienced pregnant women on H2RA + TDF.

**EVOTAZ (adult ≥ 18 years):** One tablet once daily with food.

**ATV absorption** is dependent on low gastric pH and when administered with medications that alter gastric pH, special dosing information is required. Limited data on the use of oral powder, especially in the youngest patients. Oral powder must be taken with ritonavir and food and should not be used in children < 10kg or > 25 kg. Oral powder must be mixed with food or beverage for administration and ritonavir must be given immediately afterwards. Oral powder contains phenylalanine, which can be harmful in patients with phenylketonuria.

** Mixing oral powder:** Preferable to mix with soft food. Mix packets with at least one tablespoon of food. Repeat with additional 15 mLs to drink residual mixture.

**Antacids:** Antacids and buffered medications (including buffered ddI formulations) decrease ATV concentrations if administered at the same time; ATV should be administered 2 hours before or 1 hour after these medications.

**ATV solubility** decreases as pH increases. Consult prescribing information if co-administered with an H-2 receptor antagonist or proton-pump inhibitor. Both of these classes of agents substantially decrease ATV plasma concentrations and therefore therapeutic response. PPI are not recommended in treatment-experienced patients on ATV.

**H2-Receptor Antagonists (unboosted ATV in treatment-naive patients):** H2-receptor antagonists are expected to decrease ATV concentrations and interfere with absorption. ATV 400 mg should be administered at least 2 hours before or at least 10 hours after a dose of the H2-receptor antagonist (no single dose should exceed a dose comparable to famotidine 20 mg and total daily dose should not exceed a dose comparable to famotidine 40 mg).

**H2-Receptor Antagonists (boosted ATV in treatment-naive or experienced patients):** H2-receptor antagonists are expected to decrease ATV concentrations and interfere with absorption. Dose recommendations for H2-receptor antagonists are either a ≤ 40 mg dose equivalent of famotidine twice daily (treatment-naive patients) or a ≤ 20 mg dose equivalent of famotidine twice daily (treatment-experienced patients). Dose: 300 mg ATV + 100 mg RTV should be administered simultaneously with and/or ≥ 10 hrs after the dose of H2-receptor antagonist.

**H2-Receptor Antagonists (boosted ATV with tenofovir):** In treatment-experienced patients, if TDF is used with H2-
## Drugs and Therapeutics

### Cobicistat (Cobi)

**TYBOST**
- Tablets: 150 mg
- Tablets in combination with cobicistat: EVOTAZ - 300 mg
- Darunavir + 150 mg cobicistat
- PREZCOBIX - 800 mg
- darunavir + 150 mg cobicistat
- STRIBILD - 150 mg
- elvitegravir + 150 mg cobicistat + 200 mg emtricitabine + 300 mg tenofovir

Cobicistat is available as tablets to be used as pharmacokinetic enhancer when used with EVG, ATV, DRV or in fixed-dose combination tablets (eg. Stribild, Evotaz, Prezcobix).

#### Adult Dose
- Adult dose: 150 mg once daily with EVG, ATV, or DRV (see individual agents)

#### More common effects
- Nausea, vomiting, diarrhea, abdominal pain, anorexia.
- Less common: new onset or worsening of renal impairment when used with TDF.
- Rare: rhabdomyolysis, increase in amylase and lipase.

#### Not interchangeable with ritonavir.

#### Dosing of cobicistat in patients with renal impairment:
- Do not use cobicistat with TDF in patients with CrCl < 70 mL/min because of the potential need for dose adjustments of TDF if CrCl drops below 50 mL/min.

### Darunavir (DRV)

**Neonatal/Infant Dose**
- Not approved for use in neonates/infants.

**Pediatric Dose (age < 3 years of age):** Should not be used in patients < 3 years.

**Pediatric Dose (3 < 18 years of age; ≥ 10kg):**

<table>
<thead>
<tr>
<th>Weight</th>
<th>Dose (both twice daily with food)</th>
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<tbody>
<tr>
<td>10 to &lt;11 kg</td>
<td>DRV 200 mg (2 mL) + RTV 32 mg (0.4 mL)</td>
</tr>
<tr>
<td>11 to &lt;12 kg</td>
<td>DRV 220 mg (2.2 mL) + RTV 32 mg (0.4 mL)</td>
</tr>
<tr>
<td>12 to &lt;13 kg</td>
<td>DRV 240 mg (2.4 mL) + RTV 40 mg (0.5 mL)</td>
</tr>
<tr>
<td>13 to &lt;14 kg</td>
<td>DRV 260 mg (2.6 mL) + RTV 40 mg (0.5 mL)</td>
</tr>
</tbody>
</table>

**More common effects:**
- Diarrhea, nausea, vomiting, abdominal pain, headache, fatigue.
- Less common (more severe): skin rash, including Stevens-Johnson syndrome and erythema multiforme.
- Fever and increased LFT’s. Lipid abnormalities.
- Rare: Hepatotoxicity and acute hepatitis in patients at increased risk (eg).

**Not used in combination with DRV to such patients.**

**Contraindications:**
- DRV to patients with acute hepatitis.
- DRV to patients with severe hepatic impairment.

**Precautions:**
- Many potential drug interactions as with protease inhibitors.
- Potent CYP3A4 and CYP2D6 inhibitor.

**Dosing of darunavir in patients with renal impairment:**
- Do not use darunavir with TDF in patients with CrCl < 70 mL/min because of the potential need for dose adjustments of TDF if CrCl drops below 50 mL/min.

### Other Information

**DIATRIC AND ADULT DOSING.**

<table>
<thead>
<tr>
<th>Weight</th>
<th>Dose</th>
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</thead>
<tbody>
<tr>
<td>3 to &lt;10 kg</td>
<td>DRV 200 mg (2 mL) + RTV 32 mg (0.4 mL)</td>
</tr>
<tr>
<td>10 to &lt;13 kg</td>
<td>DRV 240 mg (2.4 mL) + RTV 40 mg (0.5 mL)</td>
</tr>
<tr>
<td>13 to &lt;16 kg</td>
<td>DRV 260 mg (2.6 mL) + RTV 40 mg (0.5 mL)</td>
</tr>
</tbody>
</table>

**More common effects:**
- Nausea, vomiting, diarrhea, abdominal pain, anorexia.
- Less common: new onset or worsening of renal impairment when used with TDF.
- Rare: rhabdomyolysis, increase in amylase and lipase.

**Not interchangeable with ritonavir.

**Dosing of cobicistat in patients with renal impairment:**
- Do not use cobicistat with TDF in patients with CrCl < 70 mL/min because of the potential need for dose adjustments of TDF if CrCl drops below 50 mL/min.

**Contraindications:**
- DRV to patients with acute hepatitis.
- DRV to patients with severe hepatic impairment.

**Precautions:**
- Many potential drug interactions as with protease inhibitors.
- Potent CYP3A4 and CYP2D6 inhibitor.

**Dosing of darunavir in patients with renal impairment:**
- Do not use darunavir with TDF in patients with CrCl < 70 mL/min because of the potential need for dose adjustments of TDF if CrCl drops below 50 mL/min.
### ANTIRETROVIRALS: PEDIATRIC AND ADULT DOSING, Diana F. Clarke, Pharm.D. UPDATED July 30, 2015


<table>
<thead>
<tr>
<th>Pediatric dose (weeks to &lt; 3 months of oral solution): 50 mg per m2 of body surface area every 12 h. (Manufacturer recommends 100 mg per m2 of body surface area every 12 h. PK suggests potential for increased toxicity)</th>
<th>Neonatal/Infant dose (2 weeks to &lt; 3 months of oral solution): 50 mg per m2 of body surface area every 12 h. (Manufacturer recommends 100 mg per m2 of body surface area every 12 h. PK suggests potential for increased toxicity)</th>
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<tbody>
<tr>
<td>Infant dose (infants aged ≥ 3 months to 8 months): 100 mg per m2 of body surface area every 12 h.</td>
<td>Pediatric dose (&gt; 8 months of age): 120 mg per m2 body surface area every 12 h. Pediatric dosage range: 90-150 mg/m2 every 12 h. In treatment-naive children aged 3-21 years, 240 mg/m2 once daily (oral solution or capsules) has been used with good viral suppression.</td>
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<tr>
<td>Pediatric (ages 6 to 18 years and ≥ 20 kg and able to swallow pills) using ddl delayed release capsules: 20 kg to &lt; 25 kg: 200 mg once daily 25 kg to ≤ 60 kg: 250 mg once daily ≥ 60 kg: 400 mg once daily</td>
<td>Pediatric (ages 6 to 18 years and ≥ 20 kg and able to swallow pills) using ddl delayed release capsules: 20 kg to &lt; 25 kg: 200 mg once daily 25 kg to ≤ 60 kg: 250 mg once daily ≥ 60 kg: 400 mg once daily</td>
</tr>
<tr>
<td>Adult/adolescent dose of Delayed release capsules: &gt; 60 kg: 400 mg once daily</td>
<td>Adult/adolescent dose of Delayed release capsules: &gt; 60 kg: 400 mg once daily</td>
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<tr>
<td>Patients with hepatitis B or C, prior LFTs)</td>
<td>Most common: diarrhea, abdominal pain, nausea, vomiting Unusual: peripheral neuropathy (dose related, more common in patients with advanced disease), electrolyte abnormalities, hyperuricemia Uncommon: pancreatitis, increased LFTs; lactic acidosis and severe hepatomegaly with steatosis. Risk factors for lactic acidosis include gender (women), obesity, prolonged NRTI exposure. Retinal degeneration, retinal changes, and optic neuritis. Hepatotoxicity. Fat redistribution. Potential association with</td>
</tr>
</tbody>
</table>
| Dolasetrigravir (DTG, GS-1349572) | **Neonatal/Infant dose:** Not approved for use.  
**Pediatric dose (< 12 years):** Not approved in children < 12 years of age.  
**Pediatric dose (≥ 12 years and >40 kg and Treatment-naive/INSTI naïve):** 50 mg once daily. (With Efavirenz, FapV/r, TPV/r, or rifampin, then 50 mg twice daily.)  
Investigational dose in children > 40 kg: 50 mg once daily.  
**Adult Dose:** |  
| | **Non-cirrhotic portal hypertension.**  
**Insulin resistance and diabetes mellitus.**  
**Most frequent:** rash, insomnia  
**Unusual (more severe):** hypersensitivity reactions including rash, constitutional findings, organ dysfunction.  
**Increased LFTs especially in patients with HCV or HBC infection.**  
**Other:** Lipodystrophy.  
**Decrease in secretion of creatinine with slight increase in serum creatinine but does not affect GFR.**  
**Avoid enzyme inducers if possible.**  
**TRIUMEQ (adult ≥ 18 years): One tablet once daily (TRIUMEQ alone is not recommended for use in patients with current or past history of resistance to any components. TRIUMEQ alone is not recommended in patients with resistance associated integrase substitutions or clinically suspected integrase strand transfer inhibitor resistance because the dose of dolutegravir in TRIUMEQ is insufficient in these subpopulations.)** |  
| **Multiple drug interactions.** UGT1A1 and CYP3A substrate. Enzyme inducers may decrease DTG concentration. DTG inhibits renal transporter OCT2. DTG may increase metformin concentrations by inhibiting OCT2 (primary route of elimination of metformin). Efavirenz decreases DTG concentrations: co-administer DTG with DRV/r, ATV/r, LPV/r to counteract drug interaction. Do not administer with NVP. With Efavirenz, requires twice daily dosing of DTG. Take without regard to meals.  
Should be taken 2 hours before or 6 hours after taking cation-containing antacids or laxatives, sucralfate, oral iron supplements, oral calcium supplements, or buffered medications (eg. dilt suspension). Alternatively, DTG and iron or calcium supplements can be taken together with food.  
Poor virologic response to 50mg twice daily with Q148 mutation plus 2 or more additional INSTI mutations: L74I/M, E138A/D/K/T, G140A/S, Y143H/R, E157Q, G163E/K/D/R/S, or G193E/R.  
Patients with HBV or HCV infections and those with marked elevations in transaminases prior to treatment are at increased risk of elevated transaminases.  
Dosing in patients with hepatic impairment: No dose adjustment required for mild- moderate hepatic impairment. DTG not recommended in patients with severe hepatic impairment (no data).  
Dosing in patient with renal impairment: No dose adjustment required in INSTI-experienced patients with any degree of renal impairment or in INSTI-experienced patients with mild-moderate renal impairment. Use with caution in patients INSTI-experienced with GFR< 30mL/min. |  
| Efavirenz (EFV)  
Class: NNRTI  
SUSTIVA  
Capsules: 600 mg film-coated  
Tablets in combination with tenofovir and emtricitabine: ATRIPRA-200 mg  
ATRIPRA-300 mg  
ATRIPRA-600 mg  
**Neonatal/Infant dose:** Not approved for use.  
**For infants and children 3 months to < 3 years and > 3 kg:** recommended. (see aidsinfo.nih.gov)  
**Pediatric dose (≥ 3 years of age and weight ≥10 kg):** administered once daily  
10 to <10 kg: 200 mg  
10 to <20 kg: 200 mg  
15 to <25 kg: 250 mg  
20 to <30 kg: 300 mg  
25 to <32.5 kg: 350 mg  
32.5 to < 40 kg: 400 mg  
> 40 kg: 600 mg  
Some experts recommend 367 mg/m2 (max. dose 600 mg) to avoid underdosing.  
**Adult/adolescent dose (≥ 40 kg):** 600 mg once daily.  
**Combination Therapies (adults):**  
EFV + f-APV (adults): 700 mg f-APV + 100 mg RTV twice daily + 600 mg |  
|  
| **Non-cirrhotic portal hypertension.**  
**Insulin resistance and diabetes mellitus.**  
**Most frequent:** skin rash, incidence higher in children; central nervous system symptoms (including somnolence, insomnia, abnormal dreams, impaired concentration, confusion, hallucinations) - more common in adults.  
**Other:** increased LFT’s, hepatotoxicity.  
**Lipohypertrophy.**  
**Pregnancy category D:** Potentially teratogenic.  
**Multiple drug interactions.** CYP3A4 inducer/inhibitor (more inducer). CYP3A4 and CYP2B6 substrate.  
Only RTV boosted regimens should be used with f-APV or ATV.  
EFV and Atripla should be taken on an empty stomach. A high fat meal may increase absorption and should be avoided.  
Bedtime dosing is recommended to improve tolerability of CNS side effects.  
Capsules can be opened and added to food or small amounts of liquid. Mix capsule contents with 1-2 teaspoons of soft food or formula. After administration, and additional 2 teaspoons of food or formula to take residual dose. Administer within 30 minutes of mixing and do not eat for 2 hours.  
False positive with some cannabinoids and benzodiazepine tests have been reported in patients on EFV. |
## Emtricitabine (FTC)

Class: NRTI  
EMTRIVA  
Solution: 10 mg/ml  
Capsules: 200 mg  
Tablets in combination with tenofovir and efavirenz or rilpivirine: TRUVADA- 200 mg  
emtricitabine + 300 mg  
tenofovir  
ATRIPILA-200mg  
etricitabine + 300 mg  
tenofovir + 600 mg  
efavirenz  
COMPLERA-200mg  
etricitabine + 300mg  
tenofovir + 25 mg  
rilpivirine  

### Dosage

<table>
<thead>
<tr>
<th>Neonatal/Infant dose (age 0 to &lt; 3 months):</th>
<th>Oral solution: 3 mg per kg of body weight once daily.</th>
<th>More common: headache, diarrhea, nausea, rash, skin discoloration (hyperpigmentation) on palms and soles predominantly in non-Caucasians.</th>
<th>Can be administered without regard to food. Decrease dosage in patients with impaired renal function. Exacerbation of hepatitis B infection (in co-infected patients) when FTC is discontinued. Oral solution should be refrigerated. Can be kept at room temperature up to 77°F (25°C) if used within three months. Atripla should be administered on an empty stomach. Do not use in combination with 3TC because of similar resistance profiles and no potential additive benefit. Atripla should not be used in patients with CrCl &lt; 50 mL/min or pediatric patients &lt; 40 kg where the EVF would be excessive. Truvada should not be used in patients with CrCl &lt; 30 mL/min or patients requiring dialysis.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediatric dose (3 months-17 yrs):</td>
<td>Oral solution: 6 mg/kg once daily (max. dose 240 mg).</td>
<td>Less common (more severe): Neutropenia; lactic acidosis and severe hepatomegaly with steatosis</td>
<td></td>
</tr>
</tbody>
</table>
### Enfuvirtide (T-20)
Class: Fusion Inhibitor
**FUZEON**
Lyophilized powder for injection: 108 mg vial of ENF. Reconstitution with 1.1 mL of sterile water will deliver 90mg/mL.
Convenience Kit: 60 single use vials for SQ injection of Fuzeon (90 mg strength), vials of sterile water, reconstitution and administration syringes, alcohol wipes

**Pediatric and Adult Dosing.**

<table>
<thead>
<tr>
<th>Neonatal/Infant dose: Not approved for use in neonates/infants. Pediatric/adolescent dose (6-16 years of age): 2 mg/kg twice daily (max.dose 90 mg =1ml) SQ into upper arm, anterior thigh, or abdomen</th>
<th>Most common: Almost all patients (98%) get local injection site reactions:pain, induration, erythema, nodules, cysts, pruritis, and ecchymosis. Less common: increased rate of bacterial pneumonia; local site cellulitis (3-8%). Rare: hypersensitivity reactions: fever, nausea and vomiting, chills, increased LFTs, and hypotension. Immune-mediated reactions: primary immune complex reaction, respiratory distress, glomerulonephritis, Guillain-Barré syndrome.</th>
<th>Patients experiencing signs and symptoms consistent with hypersensitivity reactions should seek immediate medical attention. Therapy should not be restarted in these patients. Patients and caregivers should be carefully instructed in proper technique for drug reconstitution and administration of SQ injections. Reconstituted vial should be allowed to stand until the powder goes completely into solution (which could take up to 45 minutes). Do not shake. Once reconstituted Fuzeon should be injected immediately or kept refrigerated in the original vial until use. Reconstituted Fuzeon must be used within 24 hours. Injection sites should be rotated. To minimize local reactions, apply ice or heat after injection or gently massage injection site to better disperse the dose. Biojector can be used for administration.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Recommended dose for pediatric patients 6 to &lt; 18 years of age</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Weight (kg)</strong></td>
<td><strong>Dose</strong></td>
<td></td>
</tr>
<tr>
<td>16 kg to &lt; 20 kg</td>
<td>100 mg twice daily</td>
<td></td>
</tr>
<tr>
<td>20 kg to &lt; 25 kg</td>
<td>125 mg twice daily</td>
<td></td>
</tr>
<tr>
<td>25 kg to &lt; 30 kg</td>
<td>150 mg twice daily</td>
<td></td>
</tr>
<tr>
<td>≥ 30 kg</td>
<td>200 mg twice daily</td>
<td></td>
</tr>
<tr>
<td><strong>Adult dose (ARV-experienced): ETR 200 mg twice daily following a meal.</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Etravirine (ETR, TMC125)
Class: NNRTI
**INTELENCE**
Tablets: 25mg, 100 mg, 200 mg

**Pediatric and Adult Dosing.**

<table>
<thead>
<tr>
<th>Neonatal/Infant dose: Not approved for use in neonates/infants. Pediatric dose (6- &lt; 18 years of age): Not approved for use in children &lt; 6 years of age.</th>
<th>Most common: Nausea, rash. Diarrhea. Patients with a history of NNRT-associated rash do not appear to be at increased risk. Less common (more severe): Severe rash including Stevens-Johnson syndrome erythema multiforme. Hypersensitivity reaction (rash sometimes with constitutional findings, organ dysfunction including hepatic failure). Periphera neuropathy, increased LFTs.</th>
<th>Multiple drug interactions. Inducer of CYP3A4 and inhibitor of CYP2C9, CYP2C19, and Pgp. Substitute for CYP3A4, 2C9, and 2C19. ETR should not be co-administered with the following ARVs: PPV/ATV, ATV/RTV, I-APV/RTV, RTV, unboosted PIs, and any of the NNRTIs. Limited data in adults, ETR decreases RAL trough concentrations. ETR should always be taken following a meal. AUC is decreased by 50% when taken on an empty stomach. Tablets are sensitive to moisture and should be stored at room temperature in original container with desiccant. Patients unable to swallow tablets can disperse the tablets in a small amount of water. Once dispersed, stir well, and consume immediately. Rinse glass several times and consume immediately. Biojector can be used for administration.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recommended dose for pediatric patients 6 to &lt; 18 years of age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Weight (kg)</strong></td>
<td><strong>Dose</strong></td>
<td></td>
</tr>
<tr>
<td>16 kg to &lt; 20 kg</td>
<td>100 mg twice daily</td>
<td></td>
</tr>
<tr>
<td>20 kg to &lt; 25 kg</td>
<td>125 mg twice daily</td>
<td></td>
</tr>
<tr>
<td>25 kg to &lt; 30 kg</td>
<td>150 mg twice daily</td>
<td></td>
</tr>
<tr>
<td>≥ 30 kg</td>
<td>200 mg twice daily</td>
<td></td>
</tr>
<tr>
<td><strong>Adult dose</strong>: ETR 200 mg twice daily following a meal.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Fosamprenavir (FPV)
Class: PI
**LEXIVA**
Tablets: 700 mg Suspension: 50mg/ml

**Pediatric and Adult Dosing.**

<table>
<thead>
<tr>
<th>Neonatal/Infant dose: Not approved for use in neonates/infants. Pediatric dose 6 months-16 years of age (once daily dosing not recommended):</th>
<th>Most common: nausea, vomiting, diarrhea, headache, abdominal pain, skin rashes, periorbital paresthesias Unusual: life-threatening skin rashes, including Stevens-Johnson syndrome Rare: increased</th>
<th>Many potential drug interactions as with other protease inhibitors. CYP3A4 inhibitor, inducer, and substrate. Should not be taken with ETR. FPV may be taken with or without food. FPV tablets with RTV should be taken with food. Pediatric patients should take the suspension with food. Fosamprenavir is a prodrug of APV. APV is a sulfonamide and may have cross-sensitivity with other sulfonamides. Patients taking antacids or buffered ddi should take FPV at least one hour before or after antacid or ddi use.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Weight (kg)</strong></td>
<td><strong>FPV + RTV both twice daily with food</strong></td>
<td></td>
</tr>
<tr>
<td>&lt; 11 kg</td>
<td>FPV 45 mg/kg + RTV 7 mg/kg</td>
<td></td>
</tr>
<tr>
<td>11 - 15 kg</td>
<td>FPV 30 mg/kg + RTV 5 mg/kg</td>
<td></td>
</tr>
<tr>
<td>15 - 20 kg</td>
<td>FPV 15 mg/kg + RTV 3 mg/kg</td>
<td></td>
</tr>
<tr>
<td>≥ 20 kg</td>
<td>FPV 10 mg/g + RTV 3 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>
**Indinavir (IDV)**

- **Class:** PI
- **CRIXIVAN**
- **Capsules: 100 mg, 200 mg, and 400 mg**

**Neonatal/Infant dose (infants aged < 4 weeks) dose for prevention of transmission or treatment:** 2 mg/kg twice daily.

**Pediatric dose (≥ 4 weeks):** 4 mg/kg (max. 150 mg) twice daily or weight band dosing using scored tablets (wt ≥ 14 kg):

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>AM dose</th>
<th>PM dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;14-20</td>
<td>½ tab (7.5 mg)</td>
<td>½ tab (7.5 mg)</td>
</tr>
<tr>
<td>≥20-25</td>
<td>½ tab (7.5 mg)</td>
<td>1 tab (15 mg)</td>
</tr>
<tr>
<td>≥25</td>
<td>1 tab (150 mg)</td>
<td>1 tab (150 mg)</td>
</tr>
</tbody>
</table>

**Adolescent (age ≥ 16 years): Adult dose:**
- > 50 kg: 150 mg twice daily or 300 mg once daily.
- ≤ 50 kg: 4 mg/kg body weight (maximum dose 150 mg) twice daily.

**COMBIVIR** (Adolescent weight ≥ 30 kg)
- One tablet twice daily.

**TRIZIVIR** (Adolescent weight > 40 kg)
- One tablet twice daily.

**EPZICOM** (Adolescent age ≥ 16 years and weight > 50 kg)
- One tablet once daily.

**TRIUMEQ** (adult ≥ 18 years)
- One tablet once daily

**Most frequent:**
- Nausea, abdominal pain, headache, asymptomatic indirect hyperbilirubinemia (10%), lipid abnormalities.
- Blurred vision, metallic taste, alopecia, dizziness.
- Nephrolithiasis: kidney stones in 4-8% patients.
- Lipodystrophy. Rare: hyperglycemia, hepatitis.

**Most frequent: Updated July 30, 2015**

**For oral suspension, shake well prior to use. Refrigeration is not required. Dosage adjustment in patients with hepatic insufficiency recommended. Large pill burden and volume of suspension required for dosing limit use in patients.**

**Lamivudine (3TC)**

- **Class:** NRTI
- **EPIVIR, EPIVIR HBV Solution:** 10 mg/mL (EPIVIR); 5 mg/mL (Epivir HBV)
- **Capsules:** 100 mg, 200 mg, and 300 mg
- **Tablets in combination with abacavir:
  - COMBIVIR, generic-300 mg, zidovudine + 150 mg lamivudine
  - TRIZIVIR: 300 mg zidovudine + 150 mg lamivudine + 300 mg abacavir
  - EPZICOM: 300 mg lamivudine + 600 mg abacavir
  - TRIUMEQ: 50 mg**

**Neonatal/Infant dose (infants aged < 4 weeks) dose for prevention of transmission or treatment:** 2 mg/kg twice daily.

**Pediatric dose (≥ 4 weeks):**
- 140 mg FPV + 200 mg RTV twice daily OR
- 140 mg FPV + 100 mg RTV once daily OR
- 700 mg FPV + 100 mg RTV twice daily

**Protease inhibitor-experienced patient:**
- 700 mg FPV + 100 mg RTV twice daily. Once daily dosing is not recommended.

**Combination Therapies (adults):**
- FPV in combination with EFV (adults) - 700 mg FPV + 100 mg RTV twice daily + 600 mg EFV once daily OR
- 140 mg FPV + 300 mg RTV + 600 mg EFV once daily (PI naïve patients only)
- FPV in combination with maraviroc (adults): 700 mg FPV + 100 mg RTV twice daily + 150 mg MVC twice daily.

**Most frequent:**
- Nephrolithiasis.
- Abnormal LFTs.
- Hypernatremia.
- Rare: hyperglycemia, hepatitis.

**Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection.**

- **Antiretroviral:** PE
- **FPV in combination with maraviroc (adults):** 700 mg FPV + 50 mg RTV twice daily + 150 mg MVC twice daily.

- **FPV in combination with EFV (adults):**
  - 700 mg FPV + 100 mg RTV twice daily + 600 mg EFV once daily OR
  - 140 mg FPV + 300 mg RTV + 600 mg EFV once daily (PI naïve patients only)

- **FPV in combination with ritonavir (adults):**
  - 1400 mg FPV + 500 mg RTV twice daily.

- **FPV in combination with ritonavir (adults):**
  - 1400 mg FPV + 500 mg RTV twice daily + 300 mg MVC twice daily.

- **FPV in combination with ritonavir (adults):**
  - 1400 mg FPV + 1000 mg RTV twice daily + 600 mg EFV once daily OR
  - 1400 mg FPV + 300 mg RTV + 600 mg EFV once daily (PI naïve patients only)

**For oral suspension, shake well prior to use. Refrigeration is not required. Dosage adjustment in patients with hepatic insufficiency recommended. Large pill burden and volume of suspension required for dosing limit use in patients.**

**Adolescent (age ≥ 14 years):**

- **Adult dose:** One tablet once daily.

- **Adolescent weight ≥ 30 kg**
  - One tablet once daily.

- **For oral suspension, shake well prior to use.**
  - Refrigeration is not required.
  - Dosage adjustment in patients with hepatic insufficiency recommended.
  - Large pill burden and volume of suspension required for dosing limit use in patients.
<table>
<thead>
<tr>
<th>Lopinavir/Ritonavir (LPV/RTV)</th>
<th>Dolapivir + 600 mg abacavir + 300 mg lamivudine</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pediatric Oral solution:</strong> 80 mg/mL lopinavir/20 mg/mL ritonavir</td>
<td><strong>Most common: diarrhea, headache, asthenia, and nausea and vomiting.</strong> Increase in blood lipids (cholesterol and triglycerides), rash in patients on combination therapy. Rare: pancreatitis, diabetes, hyperglycemia, hepatic toxicity, spontaneous bleeding in hemophiliacs, fat redistribution. QT and PR interval prolongation. Risk of cardiotoxicity in preterm infants. Multiple drug interactions as with other protease inhibitors. CYP3A4 inhibitor and substrate. Administer solution with food to enhance bioavailability. Oral tablet can be taken with or without food. Food may help decrease any GI toxicity. If coadministered with ddi, ddi should be given one hour before or two hours after lopinavir/ritonavir. Oral solution should be kept refrigerated. Can be stored at room temperature up to 77°F (25°C) if used within 2 months. Tablets do not require refrigeration. Tablets should not be crushed or split. Dosing of LPV/RTV in patients with hepatic impairment: Caution in patients with hepatic impairment. No dosing information is currently available for children or adults with hepatic insufficiency. Pediatric oral solution contains 42.4% alcohol by volume. Once daily dosing is not recommended in children. LPV/RTV can be administered once daily (800/200 mg) in adults with less than 3 LPV resistance mutations. Do not use once daily if three or more of the following LPV resistance-associated mutations: L10F/I/R/V, K20M/N/R, L24I, L33F, M36I, I47V, G48V, I54L/T/V, V82A/C/F/S/T and I84V. Use with caution in patients with pre-existing cardiac conduction disorders or with other drugs known to prolong the PR interval.</td>
</tr>
</tbody>
</table>

### Neonatal Dose (Infants < 14 days):

- No data on appropriate dose or safety. Do not administer to neonates before a postmenstrual age of 42 weeks and a postnatal age of at least 14 days.

### Infant Dose (14 days-12 months):

- In patients not receiving concomitant NVP, EFV, FPV, or NFV: 300 mg LPV per m2/75 mg RTV per m2 twice daily. This dosing is associated with lower troughs than in adults. Frequent dose adjustments required as infant gains weight.

### Pediatric Dosing of Solution:

- **Age:** 12 months to 18 years of age (without NVP, FPV, EFV, or NFV): 300 mg/75 mg LPV/RTV per m2 twice daily with food.

### Pediatric Tablet Dosing (without NVP, FPV, EFV, or NFV):

- **Adult (age > 18 years) dose:** 200 mg LPV/25 mg RTV Tabs
- **Recommended # of 100 mg/25 mg LPV/r Tablets Twice Daily**

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>LPV/RTV Tablets</th>
<th>Target dose (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;20 kg</td>
<td>2 tabs</td>
<td>300 mg/M2/dose twice daily</td>
</tr>
<tr>
<td>&lt;20 kg</td>
<td>2 tabs</td>
<td>230 mg/M2/dose twice daily</td>
</tr>
</tbody>
</table>

### Adult (age > 18 years) dose, treatment naive patients:

- 800 mg LPV/RTV twice daily: use once daily regimen only in treatment-naive patients. Do not use once daily dosing in children or adolescents or patients receiving concomitant therapy with NVP, EFV, FPV, or NFV, or in patients with 3 or more LPV-associated mutations.

### Adult (age > 18 years) dose:

- 400 mg LPV/100 mg RTV both twice daily.

### Combination Therapies (adults):

- LPV/RTV + SQV (adults): 1000 mg SQV + 400 mg LPV/100 mg RTV both twice daily.
- LPV/RTV + maraviroc (adults): 400 mg LPV/100 mg RTV twice daily + 1500 MVC twice daily.

### Pediatric Oral Solution:

- **mg/mL ritonavir**
- **Pediatric Oral solution:** 80 mg/mL lopinavir/20 mg/mL ritonavir

### Pediatric Tablet Dosing:

- **Recommended # of 100 mg/25 mg LPV/r Tablets Twice Daily**

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>LPV/RTV Tablets</th>
<th>Target dose (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;20 kg</td>
<td>2 tabs</td>
<td>300 mg/M2/dose twice daily</td>
</tr>
<tr>
<td>&lt;20 kg</td>
<td>2 tabs</td>
<td>230 mg/M2/dose twice daily</td>
</tr>
</tbody>
</table>

### Patients receiving concomitant NVP, EFV, FPV, or NFV and weight > 35 kg, recommended dose 500 mg/125 mg LPV/RTV twice daily.

### Note:

- Consider using 3 tabs in AM, 2 tabs in PM.
- For patients receiving concomitant NVP, EFV, FPV, or NFV: Higher doses of LPV/r are required. TDM recommended.

### Related Information:


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**References:**

- Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection.
- Diana F. Clarke, Pharm.D.
### Maraviroc (MVC)
- **Class:** Entry inhibitor
- **SELENTRY Tablets:** 150, 300 mg

**Neonatal/Infant dose:** Not approved for use in neonates/infants

**Pediatric dose:** Not approved for use in children aged < 16 years.

**Adult/adolescent (age >16 years) dose:**
- **Concomitant ARVs:**
  - CYP3A inhibitors (+/- CYP3A4 inducers) including all PIs (except TPI/RTV), ketoconazole,itraconazole, clarithromycin: 150 mg twice daily.
  - Other drugs that are not strong inhibitors or inducers such as EFV, rilampin, carbamazepine, phenobarbital, and phenytoin: 600 mg twice daily.

- **NVP:**
  - Based on ANTIRETROVIRALS: PE (MVC) 400 mg (NVP) Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection.

**Total:**
- 120 mg to 1250 mg (five of the 250 mg tablets or two of the 625 mg tablets) twice daily with food.
- (Some adolescents require higher doses than adults to achieve equivalent drug exposures. Consider therapeutic drug monitoring to guide appropriate dosing).

- **Diabetes:**
  - Consider therapeutic drug monitoring to guide appropriate dosing.

**More common:**
- Cough, fever, URI infections, rash, abdominal pain, dizziness, musculoskeletal symptoms, postural hypotension.
- Less common (more severe):
  - Serious AE’s in <2% of MVC-treated adult patients. Included CV abnormalities (angina, heart failure, and MI); hepatic cirrhosis or failure, cholestatic jaundice; viral meningitis; pneumonia; myositis; osteonecrosis; rhabdomyolysis.
- Hepatotoxicity may occur with systemic allergic S&S: urticarial rash, eosinophilia, elevated IgE.

**Multiple drug interactions:**
- CYP3A4 substrate. Can be given without regard to food.
- Tropism testing is required prior to initiating therapy to exclude the presence of CXC4R4 using mixed/neutral tropic virus.
- Patients need to be instructed on how to recognize symptoms of allergic reactions or hepatotoxicity.
- Caution should be used when administering MVC to patients with underlying hepatic dysfunction or those patients co-infected with hepatitis B or C.
- Caution should be used when administering MVC to patients with underlying cardiac disease.
- Caution should be used when administering MVC to patients receiving CYP3A inhibitors who have CrCl<50 mL/min or hepatic impairment.

### Nelfinavir (NFV)
- **Class:** PI
- **VIRACEPT Tablets:** 250, 625 mg

**Neonatal/Infant dose:** Not approved for use in neonates/infants.

**Pediatric dose (age 2 to 13 years):** 45-55 mg/kg twice daily with food.

**Adult/adolescent dose:** 1250 mg (five of the 250 mg tablets or two of the 625 mg tablets) twice daily with food.

- (Some adolescents require higher doses than adults to achieve equivalent drug exposures. Consider therapeutic drug monitoring to guide appropriate dosing).

**More common:**
- Cough, fever, URI infections, rash, abdominal pain, dizziness, musculoskeletal symptoms, postural hypotension.

**Less common (more severe):**
- Serious AE’s in <2% of MVC-treated adult patients. Included CV abnormalities (angina, heart failure, and MI); hepatic cirrhosis or failure, cholestatic jaundice; viral meningitis; pneumonia; myositis; osteonecrosis; rhabdomyolysis.
- Hepatotoxicity may occur with systemic allergic S&S: urticarial rash, eosinophilia, elevated IgE.

**Multiple drug interactions as with other protease inhibitors:**
- CYP3A4 substrate. Can be given without regard to food.
- Tropism testing is required prior to initiating therapy to exclude the presence of CXC4R4 using mixed/neutral tropic virus.
- Patients need to be instructed on how to recognize symptoms of allergic reactions or hepatotoxicity.
- Caution should be used when administering MVC to patients with underlying hepatic dysfunction or those patients co-infected with hepatitis B or C.
- Caution should be used when administering MVC to patients with underlying cardiac disease.
- Caution should be used when administering MVC to patients receiving CYP3A inhibitors who have CrCl<50 mL/min or hepatic impairment.

### Nevirapine (NVP)
- **Class:** NNRTI
- **VIRAMUNE Tablets:** 200 mg, scored Extended Release: 100mg and 400 mg

**Neonatal/Infant dose (age 2-14 days):** Prophylactic dosing for PMTCT is 3 doses in the first week of life: 1° dose within 48 hours of birth, 2° dose 48 hours after the 1° dose, 3° dose 96 hours after the second dose.

- **Birth weight:** 1:5-2kg: Total Dose is 8 mg orally for all infants 1.5-2kg
- **Birth weight:** >2kg: Total Dose is 12 mg orally for all infants >2kg.

(See perinatal guidelines).

**Treatment dose not defined for neonates ≤ 14 days of age.**

**Investigational dose of 6 mg/kg twice daily (no lead-in dosing for neonates) currently under study.**

**Consider increasing to mg/m² dosing at 4 weeks of age (full neonates only).**

**Pediatric dose (15 days and older):**

- **Note:** initiate therapy with the age-appropriate dose once daily for the first 14 days of therapy. If there is no rash or untoward effect at 14 days of therapy increase to the age-appropriate dose.

**Pediatric dose < 8 years of age:**
- **200 mg per m² of body surface area per dose (max. dose 200 mg) administered twice daily**

**Pediatric dose ≥ 8 years of age:**
- **120-150 mg per m² of body surface area (max. dose 200 mg) administered twice daily.**

**More common:**
- Skin rash (some severe), sedative effect, headache, diarrhea, nausea.
- Unusual: increased LFT’s, rarely severe, life-threatening and possibly fatal hepatotoxicity.
- Rare: Stevens-Johnson syndrome, a toxic epidermal necrolysis or severe skin rash accompanied by hypersensitivity reactions (fever, arthralgia, lymphadenopathy, hepatitis, renal dysfunction).

**Multiple drug interactions:**
- CYP3A4 inducer. Can be administered without regard to food.
- For suspension: shake well. Store at room temperature.
- NVP is initiated at a lower dose and increased in a stepwise fashion (except in high risk neonates). This is to allow for auto-induction of NVP metabolism and is associated with a lower incidence of toxicity.
- NVP should not be administered to patients with moderate or severe hepatic impairment.
- NVP should not be coadministered to patients receiving alatanazivir (with or without ritonavir).
- NVP-associated skin rash usually occurs within the first 6 weeks of therapy. If rash occurs during the initial 14 day lead-in period, do not increase dose until rash resolves.
- If NVP dosing is interrupted for >14 days, NVP dosing should be restarted with once daily dosing for 14 days, followed by escalation to the full, twice daily regimen.

**When using the extended release tablets, initiate therapy with 200mg immediate release tablet given once daily for the first 14 days. Increase to 400mg ER tablet once daily if no rash or other untoward effects. In patients already...**
Adult/adolescent dose: 200 mg twice daily. Note: initiate therapy at 200 mg once daily for 14 days. Increase to full dose if no rash or untoward effects.

Pediatric dose: Extended release tablets. Using 100mg or 400 mg extended release tablets once daily. (Lead in dosing required unless already on maintenance therapy).

<table>
<thead>
<tr>
<th>BSA range (m²)</th>
<th>Viramune XR (mg)</th>
<th>Once daily</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 0.58-0.83</td>
<td>200mg (2X100mg)</td>
<td></td>
</tr>
<tr>
<td>0.84-1.16</td>
<td>300mg (3 X 100mg)</td>
<td></td>
</tr>
<tr>
<td>&gt; 1.17</td>
<td>400mg (1 X 400mg)</td>
<td></td>
</tr>
</tbody>
</table>

Adult dose: Extended release tablets - 400mg ER tablet once daily. (Lead in dosing with 200mg tablet required unless already on maintenance therapy).

Combination therapies (adults):
- NVP + LPV/RTV: Higher doses of LPV/RTV required (see above) + NVP 200 mg twice daily.
- NVP + maraviroc (adults): MVC 300 mg twice daily + 200 mg NVP twice daily.

More common: Nausea, headache, dizziness, diarrhea, fatigue, and itching.
Less common: Abdominal pain, vomiting, Worsening of LFTs in patients with hep B or hep C coinfection.
Rare: Creatine kinase elevations. Myopathy and rhabdomyolysis.

Multiple drug interactions. UGT1A1-mediated glucuronidation. UGT1A1 inducers such as tipranavir may decrease RAL concentrations while UGT1A1 inhibitors such as atazanavir may increase RAL concentrations. Etravirine decreases RAL concentration. Can be given without regard to food. Chewable tablets are more bioavailable than the 400mg film-coated tablets. These dosage forms are not interchangeable. Chewable tablets should be stored in original package with desiccant to protect from moisture. No dosage adjustment is necessary for patients with mild to moderate hepatic insufficiency. No dosing information is available for patients with severe hepatic impairment. No dosage adjustment is necessary in patients with renal impairment.

Raltegravir (MK-0518, RAL)
Class: INSTI
ISINGRESS Tablets*: 400 mg (Film-coated poloxamer tablet)
Chewable Tablets: 100 mg (scored) and 25 mg Oral Granules for Suspension: 100 mg single use packets
*Film-coated tablets, chewable tablets, and oral granules are not interchangeable.

Infant/Pediatric dose (children ≥ 4 weeks of age and 3<20 kg):

<table>
<thead>
<tr>
<th>Body Weight (kg)</th>
<th>Volume (mL) of suspension (20mg/mL when reconstituted)</th>
<th>Twice daily</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 to &lt; 4 kg</td>
<td>1 mL (20 mg)</td>
<td>3 X 25 mg</td>
</tr>
<tr>
<td>4 to &lt; 6 kg</td>
<td>1.5 mL (30mg)</td>
<td>1 X 100 mg</td>
</tr>
<tr>
<td>6 to &lt; 8 kg</td>
<td>2 mL (40mg)</td>
<td>1 X 100 mg</td>
</tr>
<tr>
<td>8 to &lt; 11 kg</td>
<td>3 mL (60mg)</td>
<td>1 X 100 mg</td>
</tr>
<tr>
<td>11 to &lt; 14 kg</td>
<td>4 mL (80mg)</td>
<td>1 X 100 mg</td>
</tr>
<tr>
<td>14 to &lt; 20 kg</td>
<td>5 mL (100mg)</td>
<td>1 X 100 mg</td>
</tr>
</tbody>
</table>

Pediatric dose:
- Children 2 to < 6 years of age:
  - Chewable tablets: weight based to maximum 300 mg twice daily (see Table)
- Children 6 to < 12 years of age:
  - <25 kg: Chewable tablet twice daily to maximum of 300 mg twice daily (see table)
  - ≥25 kg: 400 mg film-coated tablet twice daily OR Chewable tablets (see Table)

Chewable Tablets Age 2 to < 12 years of age

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>RAL Dose Twice daily</th>
<th># Chewable Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 to &lt; 14</td>
<td>75 mg</td>
<td>3 X 25 mg</td>
</tr>
<tr>
<td>14 to &lt; 20</td>
<td>100 mg</td>
<td>1 X 100 mg</td>
</tr>
<tr>
<td>20 to &lt; 28</td>
<td>150 mg</td>
<td>1.5 X 100 mg</td>
</tr>
<tr>
<td>28 to &lt; 40</td>
<td>200 mg</td>
<td>2 X 100 mg</td>
</tr>
<tr>
<td>≥ 40</td>
<td>300 mg</td>
<td>3 X 100 mg</td>
</tr>
</tbody>
</table>

Adolescent (age ≥ 12)/ Adult dose: 400 mg film-coated tablet twice daily.

Based on Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection http://www.Aidsinfo.nih.gov
<table>
<thead>
<tr>
<th><strong>Rilpivirine (TMC 278)</strong></th>
<th><strong>SAQUNAVIR (SQV)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Class: NNRTI</td>
<td>Class: PI</td>
</tr>
<tr>
<td>Ritonavir (RTV)</td>
<td>NORVIR</td>
</tr>
<tr>
<td>Oral solution: 80 mg/ml</td>
<td>Gel Capsules: 100mg</td>
</tr>
<tr>
<td>Capsules: 200 mg</td>
<td>Tablets: 500 mg</td>
</tr>
<tr>
<td>Pediatric dose: Not approved for use in children.</td>
<td>Investigational dose in tx-experienced children: SQV must be boosted with RTV or LPV/RTV.</td>
</tr>
<tr>
<td>Adult dose (ARV-naive patients only and HVL ≤ 100,000 copies/mL): 25 mg once daily.</td>
<td>&lt; 2 years of age: Not recommended.</td>
</tr>
<tr>
<td>Adult dose (virologically suppressed with HVL &lt; 50 copies/mL and no history of virologic failure or resistance to RPV or other ARVs and currently on their first or second regimen): 25 mg once daily.</td>
<td>2 years of age: conditional dosing based on limited data:</td>
</tr>
<tr>
<td>COMPLERA (adults): One tablet once daily.</td>
<td><strong>SQV + LPV/RTV investigational dose (Children ≥ 7 years of age for</strong></td>
</tr>
<tr>
<td></td>
<td>**</td>
</tr>
<tr>
<td>More common: insomnia, headache, rash.</td>
<td>Most frequent: diarrhea, abdominal pain, headache and nausea.</td>
</tr>
<tr>
<td>Less common: depression, mood changes.</td>
<td>Less common: lipodystrophy, elevated transaminases, hyperlipidemia.</td>
</tr>
<tr>
<td>Multiple drug interactions. Substrate for CYP3A. Should be taken with a meal of at least 500 calories. Do not use with other NNRTIs. Do not use with proton pump inhibitors. Antacids should only be taken at least 2 hours before or at least 4 hours after rilpivirine. H2 antagonists should be taken at least 12 hours before or 4 hours after RPV. Use rilpivirine with caution when coadministered with a drug with a known risk of torsade de pointes. Do not use in patients with HVL &gt; 100,000 copies/mL because these patients are at increased risk of virologic failure. No dosage adjustment is necessary in patients with mild or moderate hepatic impairment. No dose adjustment is required in patients with mild or moderate renal impairment. Use with caution in patients with severe renal impairment.</td>
<td>Multiple drug interactions as with other protease inhibitors. CYP3A4 and CYP2D6 inhibitor. CYP3A4 and CYP1A2 inducer. Administration with food increases absorption and helps decrease gastrointestinal side effects. Oral capsules should be kept refrigerated. Can be stored at room temperature up to 77° F (25°C) if used within 30 days. Tablets are heat stable. For oral solution: keep at room temperature and store in original container. Oral solution has limited shelf-life (6 months). Techniques to increase tolerance: mix oral solution with milk, chocolate milk, pudding, or ice cream. Taste buds before dosing with ice chips, popsicles, or frozen juice concentrates. Coat mouth with peanut butter. Follow dose with maple syrup, cheese or gum. Do not administer with cobicistat or use in combination with drugs that contain cobicistat.</td>
</tr>
</tbody>
</table>

**Dosing information for specific PI.**

**SQV + LPV/RTV investigational dose (Children ≥ 7 years of age for**
### Salvage Therapy

**SQV 750 mg/m² (max 1600 mg)** OR
**SQV 50 mg/kg + LPV/RTV, both twice daily.**

**Adult/adolescent dose (age > 16 yrs):** Should only be used in combination with RTV or LPV/RTV.

**Combination therapies (adults):**
- SQV + RTV (adults): SQV 1000mg + RTV 100mg twice daily.
- SQV + LPV/RTV (adults): SQV 1000 mg + LPV/RTV 400 mg twice daily.

### Stavudine (d4T)

**Class:** NRTI  
**ZERIT, generic**

**Oral solution:** 1 mg/ml  
**Capsules:** 15, 20, 30, 40 mg

**Neonatal/infant dose (age birth to 13 days):**  
0.5 mg/kg every 12 hours.

**Pediatric dose (age 14 days to wt < 30 kg):**  
1 mg/kg twice daily.

**Adult/adolescent dose (wt > 30 kg):**  
30 mg twice daily.

**Side effects:**
- Most frequent: headache, GI disturbances, skin rashes  
- Uncommon: pancreatitis, peripheral neuropathy, fat maldistribution, lipoatrophy.
- Rare: lactic acidosis, hepatic steatosis, rapidly progressive ascending neuromuscular weakness, mitochondrial toxicity, insulin resistance/diabetes mellitus.

**Can be administered without regard to food.**  
**For oral solution: Shake well and keep refrigerated.**

### Tenofovir (TDF)

**Class:** NRTI  
**VIREAD**

**Oral powder:** 40 mg per 1 gram of oral powder (1 level scoop= 1 gram of oral powder)  
**Tablets:** 150 mg, 200 mg, 250 mg, and 300 mg

**Tablets in combination with emtricitabine and efavirenz or rilpivirine:**
- TRUVADA-200 mg emtricitabine + 300 mg tenofovir  
- ATRIPLA-200 mg emtricitabine + 300 mg tenofovir + 600 mg efavirenz  
- COMPLERA-200mg emtricitabine + 300 mg tenofovir + 25 mg rilpivirine

**Neonatal/infant dose:** Not approved for use in neonates/infants.

**Pediatric dose:** 22 years to <12 years of age*: 8 mg/kg/dose once daily.

**Oral powder table:**

<table>
<thead>
<tr>
<th>Body Weight (Kilogram)</th>
<th>Oral Powder dose (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.4-11.6</td>
<td>2</td>
</tr>
<tr>
<td>11.7-14.8</td>
<td>4</td>
</tr>
<tr>
<td>15.0-17.8</td>
<td>6</td>
</tr>
<tr>
<td>18.0-20.8</td>
<td>8</td>
</tr>
<tr>
<td>21.0-23.8</td>
<td>10</td>
</tr>
<tr>
<td>24.0-26.8</td>
<td>3</td>
</tr>
<tr>
<td>27.0-30.0</td>
<td>5</td>
</tr>
<tr>
<td>30.1-33.0</td>
<td>7</td>
</tr>
</tbody>
</table>

**Side effects:**
- More common: nausea, diarrhea, vomiting, and flatulence.
- Less common (more severe): lactic acidosis, and severe hepatomegaly with steatosis, including fatal cases have been reported with NRTIs.
- Rare (unknown): tenofovir caused bone toxicity (reduced bone mineral density) in both adults and children on chronic therapy. Renal toxicity including increases in serum creatinine, BUN, glycosuria, proteinuria, phosphaturia, and/or calcium and decreases in serum phosphate has been observed in animals at high doses. Renal tubular dysfunction has been reported in patients on TDF.

**Can be taken without regard to food although a high fat meal increases absorption.**

**For oral solution:** Shake well and keep refrigerated. Stable for 30 days.

**Dosing of TDF in patients with renal insufficiency:**
- Decreased dosage should be used in patients with impaired renal function. Consult manufacturer prescribing information for adjustment of dosage in accordance with CrCl.
- Concerns about decreased bone mineral density in prepubertal patients and those in early puberty (Tanner stages 1-2)
ANTIRETROVIRALS: PEDIATRIC AND ADULT DOSING. Diana F. Clarke, Pharm.D. UPDATED July 30, 2015

Table Dosing Table: ≥ 2 and weight ≥ 17 kg:

<table>
<thead>
<tr>
<th>Daily Weight (kg)</th>
<th>Tablets Once Daily</th>
</tr>
</thead>
<tbody>
<tr>
<td>17 ≤ 22</td>
<td>200 mg</td>
</tr>
<tr>
<td>22 ≤ 35</td>
<td>300 mg</td>
</tr>
<tr>
<td>≥35</td>
<td>500 mg</td>
</tr>
</tbody>
</table>

Adolescent (age ≥ 12 years and ≥ 35 kg)*: 300 mg once daily.

*Avoid use in prepubertal children.

Adult dose: 300 mg once daily.

TRUVADA (adults): One tablet once daily

ATRIPLA (adults): One tablet once daily.

COMPLERA (adults): One tablet once daily.

Combination therapies:

TDF + ddI: Combination should be avoided if possible. TDF increases ddI concentration and may result in increased toxicity.

TDF + ATV (adults): 300 mg ATV + 100 mg RTV + 300 mg TDF, all once daily. Only ATV boosted with RTV should be used with TDF.

Tipranavir (TPV)

Class: PI

APTIVUS Capsules: 250 mg Pediatric Oral Solution: 100 mg TPV per ml


Pediatric dose (age 2-18 years) PI-experienced patients: Must be boosted- RTV.

BSA dosing: 375 mg TPV per m2 per dose + 150 mg RTV per m2 per dose, both twice daily. (Max. TPV 500 mg/RTV 200 mg twice daily)

Weight-Based dosing: 14 mg TPV per kg per dose + 6 mg RTV per kg per dose, both twice daily. (Max. dose TPV 500 mg/RTV 200 mg twice daily)

Adult dose PI-experienced patients: 500 mg (two 250 mg capsules) + 200 mg RTV twice daily.

Combination therapies (adults):

TPV/RTV + maraviroc: 500 mg TPV + 200 mg RTV both twice daily + MVC 300 mg twice daily.

Most frequent: diarrhea, nausea, fatigue, headache, rash (more common in children), vomiting, Lab abnormalities: elevated LFT’s, cholesterol, and triglycerides.

Less common: lipodystrophy; clinical hepatitis and hepatic decompensation including some fatalities. Epistaxis. Rare: hyperglycemia. Possible association with increased risk of intracranial hemorrhage.

Multiple drug interactions as with other protease inhibitors. CYP3A4 inducer and substrate. Should not be taken with ETR.

Should not be used in combination with other PIs (except RTV).

Can be taken without regard to food. However, RTV should be taken with food and the combination may be better tolerated with food.

TPV should only be used boosted with RTV in PI-experienced patients.

TPV contains a sulfonamide component and may have cross-sensitivity with other sulfonamides. Should be used with caution in patients with sulfonamide allergy.

Oral solution should be stored at room temperature. Must be used within 60 days after first opening bottle.

Oral solution contains 116 IU vitamin E per ml.

Capsules should be refrigerated. Can be kept at room temperature up to 77°F (25°C) if used within two months.

TPV contraindicated in patients with moderate to severe hepatic insufficiency.

TPV should be used with caution in patients who are at risk of increased bleeding from trauma, surgery, or receiving medications known to increase the risk of bleeding.
**Zidovudine (ZDV, AZT)**
Class: NRTI

**RETROVIR, generic**
Syrup: 10 mg/ml
Capsules: 100 mg
Tablets: 300 mg
Tablets in combination with lamivudine and abacavir:
COMBIVIR, generic - 300 mg zidovudine + 150 mg lamivudine
TRIZIVIR - 300 mg zidovudine + 150 mg lamivudine + 300 mg abacavir

Concentrate for injection, for IV infusion: 10 mg/ml

---

### Zidovudine: Neonates***

<table>
<thead>
<tr>
<th>Gestational Age (Weeks)</th>
<th>Initial Oral Dose Twice daily Dosing</th>
<th>Continuation Oral Dose Twice daily Dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤35 weeks</td>
<td>Birth to age 4 weeks: 4mg/kg/dose</td>
<td>Age &gt; 4 weeks: 12 mg/kg/dose (If used for PMTCT continue at 4 mg/kg/dose to finish 4-6 weeks of PMTCT. Do not increase to continuation dose)</td>
</tr>
<tr>
<td>≥30 to &lt;35 weeks</td>
<td>Birth to age 2 weeks: 2 mg/kg/dose Age 2 weeks to 6-8 weeks: 3mg/kg/dose</td>
<td>Age &gt; 6-8 weeks: 12 mg/kg/dose***</td>
</tr>
<tr>
<td>≥30 weeks</td>
<td>Birth to age 4 weeks: 2 mg/kg/dose Age 4 weeks to 8-10 weeks: 3mg/kg/dose</td>
<td>Age &gt; 8-10 weeks: 12 mg/kg/dose***</td>
</tr>
</tbody>
</table>

---

**Most frequent:** hematologic toxicity including neutropenia and anemia, headache, malaise, nausea, vomiting, and anorexia. Unusual: myopathy (associated with prolonged use), and liver toxicity. Rare: lactic acidosis with hepatic steatosis.

**Can be administered without regard to food.**
Decrease dosage in patients with severe renal or hepatic dysfunction.

- For intravenous solution: Dilute with 5% dextrose injection to concentration < 4 mg/ml; refrigerated diluted solution stable for 24 hours.
- Substantial granulocytopenia or anemia may necessitate interruption of therapy until marrow recovery is observed; use of erythropoetin, filgrastim, or transfusion may be necessary in some patients.
- Bone marrow suppressive/cytotoxic agents including ganciclovir, interferon alpha, and ribavirin may increase hematologic toxicity of ZDV.
- Doxorubicin use should be avoided.
- Combivir and Trizivir (fixed-dose combination products) should not be used in patients with CrCl < 50 mL/min, patients on dialysis, or patients with impaired hepatic function.

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**Premature infants:** Investigational dose. Careful clinical assessment of the infant, evaluation of hepatic and renal function, and review of concomitant medications, should be performed prior to increasing zidovudine dose to that recommended for full-term infants.

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### Infant/Child dose (Age > 35 weeks post conception and at least 4 weeks post-delivery):

**Weight band dosing:**

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>Twice-Daily Dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 to &lt;8 kg</td>
<td>12 mg/kg</td>
</tr>
<tr>
<td>9 to &lt;30 kg</td>
<td>9 mg/kg</td>
</tr>
<tr>
<td>≥30 kg</td>
<td>300 mg</td>
</tr>
</tbody>
</table>

**Body surface area dosing:** 180-240 mg/ m² every 12 hours

**Adult/adolescent dose (age > 18 yrs):** 300 mg twice daily.

**COMBIVIR (Adolescent weight ≥ 30 kg/ Adult dose):** One tablet twice daily.

**TRIZIVIR (Adolescent weight ≥ 40 kg/ Adult dose):** One tablet twice daily.

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**Updated July 30, 2015**


**Most frequent:** hematologic toxicity including neutropenia and anemia, headache, malaise, nausea, vomiting, and anorexia. Unusual: myopathy (associated with prolonged use), and liver toxicity. Rare: lactic acidosis with hepatic steatosis.

**Can be administered without regard to food.**
Decrease dosage in patients with severe renal or hepatic dysfunction.

- For intravenous solution: Dilute with 5% dextrose injection to concentration < 4 mg/ml; refrigerated diluted solution stable for 24 hours.
- Substantial granulocytopenia or anemia may necessitate interruption of therapy until marrow recovery is observed; use of erythropoetin, filgrastim, or transfusion may be necessary in some patients.
- Bone marrow suppressive/cytotoxic agents including ganciclovir, interferon alpha, and ribavirin may increase hematologic toxicity of ZDV.
- Doxorubicin use should be avoided.
- Combivir and Trizivir (fixed-dose combination products) should not be used in patients with CrCl < 50 mL/min, patients on dialysis, or patients with impaired hepatic function.

---

**Premature infants:** Investigational dose. Careful clinical assessment of the infant, evaluation of hepatic and renal function, and review of concomitant medications, should be performed prior to increasing zidovudine dose to that recommended for full-term infants.