Hepatic Dose Adjustments

**Agent(s)**

**TDF/FTC/**(Atripla®)

**Dosing Form**

TDF tab, 300 mg; FTC tab, 200 mg; 240 mL soln (20 mg/mL)

**Comments**

Children: 300 mg/200 mg one tablet or 240 mL soln of (20 mg/mL) once daily

Adults: 300 mg/200 mg one tablet or 240 mL soln of (20 mg/mL) once daily

**Special Considerations**

- **Hepatic dysfunction:** Consider reductions in hepatic function in patients with chronic liver disease or in patients with acute liver disease. Adjust dose as needed based on laboratory data.
- **Renal dysfunction:** No dose adjustment required. Dose is the same in patients with eGFR > 60 mL/min/1.73 m².
- **Pregnancy:** TDF/FTC is not recommended in pregnancy due to potential for developmental toxicity.
- **Safety Data Summary:** TDF/FTC should be used with caution in patients with severe hepatic impairment due to potential for drug accumulation and toxicities.

**Dolutegravir (Tivicay®) + tenofovir + emtricitabine (Triumeq®)**

**Dosing Form**

ATV 50 mg tab, 300 mg soln (300 mg/mL); 4 mL soln (125 mg/mL)

**Comments**

- **Hepatic dysfunction:** Consider reductions in hepatic function in patients with chronic liver disease or in patients with acute liver disease. Adjust dose as needed based on laboratory data.
- **Renal dysfunction:** No dose adjustment required. Dose is the same in patients with eGFR > 60 mL/min/1.73 m².
- **Pregnancy:** Dolutegravir is not recommended in pregnancy due to potential for developmental toxicity.
- **Safety Data Summary:** Dolutegravir should be used with caution in patients with severe hepatic impairment due to potential for drug accumulation and toxicities.

**ARV Therapy in Adults & Adolescents**

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**This resource summarizes information from the Department of Health and Human Services (DHHS) guidelines referenced below. Critical information regarding antiretroviral agents currently approved for use in adults and adolescents is included. Information summarized includes antiretroviral dosing (including renal and hepatic dose recommendations), available dosage forms, side effects, and important patient (pt) counseling points. Unless otherwise noted, information is adapted from the Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents.**

**Fact Sheet: Pharmaceutical Company Co-Op/Pharmacy Programs (CAP)**

**See following websites for additional information regarding antiretroviral agents currently approved for use in adults and adolescents:**

- www.AIDSmeds.com
- www.FDA.gov
- www.FCAETC.org
- www.fda.gov/Safety/MedWatch/HowToReport/default.htm

**See Table of ARV guidelines for dosing schemes for antiretroviral agents currently approved for use in adults and adolescents.**

2. **Emtricitabine** may replace lamivudine and vice versa (co-formulation is major determining factor).

3. Once daily treatment not recommended in pregnancy. See Panel on Antiretroviral Guidelines for Adults and Adolescents (PAGA) guidelines for recommendations in pregnant patients.

4. **Renal Dosing for Combo Products**

- Denotes combination product.

5. **Triumeq®** is not recommended in pregnancy due to potential for developmental toxicity.

6. **Nelfinavir mesylate** is not recommended in pregnant patients due to potential for developmental toxicity.

7. **Darunavir** is not recommended in pregnant patients due to potential for developmental toxicity.

8. **Atazanavir** is not recommended in pregnant patients due to potential for developmental toxicity.

9. **Amprenavir** is not recommended in pregnant patients due to potential for developmental toxicity.

10. **Saquinavir** is not recommended in pregnant patients due to potential for developmental toxicity.

11. **Lopinavir/ritonavir or lopinavir/ritonavir** is not recommended in pregnant patients due to potential for developmental toxicity.

12. **Stavudine** is not recommended in pregnant patients due to potential for developmental toxicity.

13. **Efavirenz** is not recommended in pregnant patients due to potential for developmental toxicity.

14. **Abacavir** is not recommended in pregnant patients due to potential for developmental toxicity.

15. **Nevirapine** is not recommended in pregnant patients due to potential for developmental toxicity.

16. **Pharmacokinetic Enhancers**

- **Nevirapine** is not recommended in pregnant patients due to potential for developmental toxicity.

17. **Atazanavir** is not recommended in pregnant patients due to potential for developmental toxicity.
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5. **Tenofovir (Viread®, TDF)**
6. **Stavudine (Zerit®, d4T)**

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**NRTIs (Continued)**

- **Didanosine (Videx®, EC), ddi**
  - (d4T-DFMO-sa-see)
  - 15. See Video and Videx® 3TC Prescribing information available online at www.viavst dataSize.com for dosage forms, adverse effects and other important points.

- **Emtricitabine (Emtriva®, FTC)**
  - (em-THRI-SF-ih-gin-eh, FTC)
  - Also available in combination products: Truvada®, Atripla®, Complera®, Ritek®, and Edurant®.
  - Adult dose: 200 mg once daily or 150 mg po bid.
  - Important Points:
    - Avoid abrupt withdrawal to prevent exacerbation.
    - For treatment-experienced patients with HBeAg positive disease or HBeAg negative disease.
    - Not recommended for treating chronic hepatitis B virus infection alone.

- **Lamivudine (Epivir®, 3TC)**
  - (la-MI-vu-deen)
  - Also available in combination products: Truvada®, Atripla®, Complera®, and Ritek®.
  - Adult dose: 300 mg po once daily or 150 mg po bid.
  - Important Points:
    - Avoid abrupt withdrawal to prevent exacerbation.
    - For treatment-experienced patients with HBeAg positive disease or HBeAg negative disease.
    - Not recommended for treating chronic hepatitis B virus infection alone.

- **Tenofovir (Viread®, TDF)**
  - (te-NOE-fi-vur)
  - Also available in combination products: Truvada®, Atripla®, Complera®, Ritek®, and Edurant®.
  - Adult dose: 200 mg once daily or 150 mg po bid.
  - Important Points:
    - Avoid abrupt withdrawal to prevent exacerbation.
    - For treatment-experienced patients with HBeAg positive disease or HBeAg negative disease.
    - Not recommended for treating chronic hepatitis B virus infection alone.

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**PROTEASE INHIBITORS (PIs)**

- **Class adverse effects:**
  - glucose: 1 lymph (lips with and ATV and DRV), lipodystrophy, 1 F & L (fat & lip), 1 D (drug) underlying conditions.
  - Rarely used

- **AZT**
  - (CA-TRIZ-uh-
    - Also available in combination products: Complera®, Truvada®, Atripla®, and Edurant®.
    - Adult dose: 400 mg once daily or 200 mg po tid.
    - Important Points:
      - Also available in combination product: Atripla®
      - Note: Do not use if ATPA 540 in pregnancy.

- **Atazanavir (Reyataz®, ATV)**
  - (ah-TAHZ-uh-nuh-vir)
  - Also available in combination products: Complera®, Truvada®, Atripla®, and Edurant®.
  - Adult dose: 300 mg po once daily or 200 mg po tid.
  - Important Points:
    - Also available in combination product: Atripla®
    - Note: Do not use if ATPA 540 in pregnancy.

- **Darunavir (Prezista®, DRV)**
  - (dahr-uh-NAH-vur)
  - Also available in combination product: Atripla®
  - Adult dose:
    - 800 mg + RTV 100 mg po bid (PI-exp or PI-naïve; in combination with other NRTIs)
    - 600 mg + RTV 100 mg po bid (ARV-naïve or ARV-exp; in combination with other NRTIs)
  - Important Points:
    - Also available in combination product: Atripla®
    - Note: Do not use if ATPA 540 in pregnancy.

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**NRTI Combinations**

- **Trizivir® (triz-a-veer)**
  - (triz-AH-veer)
  - Also available in combination product: Atripla®
  - Adult dose: 200 mg once daily or 100 mg po bid.
  - Important Points:
    - Also available in combination product: Atripla®
    - Note: Do not use if ATPA 540 in pregnancy.

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**ENTRY INHIBITORS**

- **Fusion Inhibitor**
  - (fu-ZHE-shun)
  - Also available in combination product: Atripla®
  - Adult dose:
    - 25 mg + RTV 100 mg po bid (PI-exp or PI-naïve; in combination with other NRTIs)
  - Important Points:
    - Also available in combination product: Atripla®
    - Note: Do not use if ATPA 540 in pregnancy.

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**CCR5 Inhibitor**

- **Maraviroc (Coryncept®, MVC)**
  - (mah-RAH-vee-rahk)
  - Adult dose:
    - 200 mg po (orally) (PI-exp or PI-naïve; in combination with other NRTIs)
  - Important Points:
    - Also available in combination product: Atripla®
    - Note: Do not use if ATPA 540 in pregnancy.

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**Maraviroc Dosing**

- **Combination Medications**
  - See Video and Maraviroc® Prescribing Information available online at www.viavst dataSize.com for dosage forms, adverse effects and other important points.

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**INTEGRASE STRAND TRANSFER INHIBITORS (INSTIs)**

- **Dolutegravir (Tivicay®, DTG)**
  - (doo-TEG-ray-vur)
  - Adult dose:
    - 50 mg po once daily (ART-naive or exp; in combination with other NRTIs)
  - Important Points:
    - Also available in combination product: Atripla®
    - Note: Do not use if ATPA 540 in pregnancy.

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**PHARMACOKINETICS (PK) ENHANCERS**

- **Cobicistat (Tybost®, CBI)**
  - (COB-uh-sih-STAT)
  - Adult dose:
    - 150 mg po once daily (PI-exp or PI-naïve; in combination with other NRTIs)
  - Important Points:
    - Also available in combination product: Atripla®
    - Note: Do not use if ATPA 540 in pregnancy.

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**INTERACTIONS**

- **Drug-drug interactions**
  - See DHHS Guidelines and www.hiv-druginteractions.org for more detail.

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**SAFETY AND TOLERABILITY**

- **Side effects**
  - Please see DHHS Guidelines and www.hiv-druginteractions.org for more detail.

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**ADDITIONAL INFORMATION**

- **Additional information**
  - See DHHS Guidelines and www.hiv-druginteractions.org for more detail.

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**FOR MORE INFORMATION**

- **Resources**
  - See DHHS Guidelines and www.hiv-druginteractions.org for more detail.

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**REFERENCES**

- **References**
  - See DHHS Guidelines and www.hiv-druginteractions.org for more detail.

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**CONTACT INFORMATION**

- **Contact information**
  - See DHHS Guidelines and www.hiv-druginteractions.org for more detail.