

- Do not breastfeed if you have HIV-1 or if you think you have recently become infected with HIV-1 because of the risk of passing HIV-1 to your baby.
- If you take emtricitabine and tenofovir disoproxil fumarate tablets for HIV-1 PEP, talk with your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medicines may interact with emtricitabine and tenofovir disoproxil fumarate tablets. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine. **Do not start a new medicine without telling your healthcare provider.** Your healthcare provider can tell you to take it, if you take emtricitabine and tenofovir disoproxil fumarate to treat HIV-1 infection, you need to take other HIV-1 medicines. Your healthcare provider will tell you what medicines to take and how to take them.

- Take emtricitabine and tenofovir disoproxil fumarate tablets 1 time each day with or without food.
- Children who take emtricitabine and tenofovir disoproxil fumarate tablets are prescribed a lower strength tablet than adults. Children should swallow the emtricitabine and tenofovir disoproxil fumarate tablets. Tell your healthcare provider if your child cannot swallow the tablet, because they may need a different HIV-1 medicine.
- Your healthcare provider will change the dose of emtricitabine and tenofovir disoproxil fumarate tablets as needed based on your child's weight.

Do not change your dose or stop taking emtricitabine and tenofovir disoproxil fumarate tablets without first talking with your healthcare provider. Stay under a healthcare provider's care when taking emtricitabine and tenofovir disoproxil fumarate tablets. Do not miss a dose of emtricitabine and tenofovir disoproxil fumarate tablets.

- If you take too much emtricitabine and tenofovir disoproxil fumarate tablets, call your healthcare provider or go to the nearest hospital emergency room right away.
- When you emtricitabine and tenofovir disoproxil fumarate tablets supply starts to run low, get more from your healthcare provider or pharmacy.
- If you are taking emtricitabine and tenofovir disoproxil fumarate tablets for treatment of HIV-1, the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to emtricitabine and tenofovir disoproxil fumarate tablets and become harder to treat.
- If you are taking emtricitabine and tenofovir disoproxil fumarate tablets for HIV-1 PEP, missing doses increases your risk of getting HIV-1 infection.

What are the possible side effects of emtricitabine and tenofovir disoproxil fumarate tablets?

- Emtricitabine and tenofovir disoproxil fumarate may cause serious side effects, including:**
- **See "What is the most important information I should know about emtricitabine and tenofovir disoproxil fumarate tablets?"**
 - **New or worse kidney problems, including kidney failure.** Your healthcare provider should do blood and urine tests to check your kidneys before you start and during treatment with emtricitabine and tenofovir disoproxil fumarate tablets. Your healthcare provider may tell you to take emtricitabine and tenofovir disoproxil fumarate tablets less often, or to stop taking emtricitabine and tenofovir disoproxil fumarate tablets if you get new or worse kidney problems.
 - **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when taking medicines to treat HIV-1 infection. Your immune system may get stronger and bring to light infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having any new symptoms after starting your HIV-1 medicine.
 - **Bone problems** include bone pain, or softening or thinning of bones, which may lead to fractures. Your healthcare provider may need to do tests to check your bones.
 - **Too much lactic acid in your blood (lactic acidosis).** Too much lactic acid is a serious but rare medical emergency that can lead to death. Tell your healthcare provider right away if you get these symptoms: weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, stomach pain with nausea and vomiting, cool or blue hands and feet, feel dizzy or lightheaded, or a fast or abnormal heartbeat.
 - **Severe liver problems.** In rare cases, severe liver problems can happen that can lead to death. Tell your healthcare provider right away if you get these symptoms: dark "tea-colored" urine, light-colored stools, loss of appetite for several days or longer, nausea, or stomach-area pain.

- The most common side effects of emtricitabine and tenofovir disoproxil fumarate tablets for treatment of HIV-1 include:
- diarrhea
 - dizziness
 - headache
 - indigestion
 - rash
 - depression
 - problems sleeping
 - abnormal dreams

Common side effects in people who take emtricitabine and tenofovir disoproxil fumarate tablets for HIV-1 PEP include:

- headache
- stomach-area (abdomen) pain
- decreased weight

- These are not all the possible side effects of emtricitabine and tenofovir disoproxil fumarate tablets. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
- How should I store emtricitabine and tenofovir disoproxil fumarate tablets?**
- Store Emtricitabine and Tenofovir Disoproxil Fumarate tablets at room temperature between 68°F to 77°F (20° to 25°C).
 - Keep Emtricitabine and Tenofovir Disoproxil Fumarate tablets in its original container.
 - Keep the container tightly closed.
 - Do not use Emtricitabine and Tenofovir Disoproxil Fumarate tablets if seal over bottle opening is broken or missing.

Keep emtricitabine and tenofovir disoproxil fumarate tablets and all other medicines out of reach of children.

General information about Emtricitabine and Tenofovir Disoproxil Fumarate tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use emtricitabine and tenofovir disoproxil fumarate for a condition for which it was not prescribed. Do not give emtricitabine and tenofovir disoproxil fumarate to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about emtricitabine and tenofovir disoproxil fumarate that is written for health professionals.

What are the ingredients in emtricitabine and tenofovir disoproxil fumarate?

Active ingredients: emtricitabine and tenofovir disoproxil fumarate.

Inactive ingredients: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and prepolysilized starch (gluten free). The tablets are coated with Opasry white K-1-7000 which contains hypromellose 2910, polyethylene glycol 400 (macrogol) and titanium dioxide.

Distributed by:
Strides Pharma Inc.
Bridgewater, NJ 08807

For more information about Emtricitabine and Tenofovir Disoproxil Fumarate Tablets, call Strides Pharma Inc. at 1-877-244-9825 or go to www.strides.com.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Revised: 05/2025

Dispense with Medication Guide available at: www.strides.com/etdf-tablets/

8.5 Genetic Use:
The drug label for emtricitabine and tenofovir disoproxil fumarate tablets should be modified in HIV-infected adult individuals with estimated creatinine clearance of 30-40 mL/min. Emtricitabine and tenofovir disoproxil fumarate tablets are contraindicated in individuals with estimated creatinine clearance below 30 mL/min and in individuals with end-stage renal disease requiring dialysis. (See Dosage and Administration 2.6).

8.6 Renal Impairment:
The drug label for emtricitabine and tenofovir disoproxil fumarate tablets should be modified in HIV-infected adult individuals with estimated creatinine clearance of 30-40 mL/min. Emtricitabine and tenofovir disoproxil fumarate tablets are contraindicated in individuals with estimated creatinine clearance below 30 mL/min and in individuals with end-stage renal disease requiring dialysis. (See Dosage and Administration 2.6).

8.7 HIV-1 PEP:
Emtricitabine and tenofovir disoproxil fumarate tablets for HIV-1 PEP is not recommended in HIV-1 infected individuals with estimated creatinine clearance below 30 mL/min. If a decrease in estimated creatinine clearance is observed in emtricitabine and tenofovir disoproxil fumarate tablets in pediatric subjects weighing 17 kg and above not available. The dosage recommendations of emtricitabine and tenofovir disoproxil fumarate tablets for HIV-1 PEP in this population is based on safety and effectiveness data from the ATN133 trial (see Use in Specific Populations 8.6) and known pharmacokinetic information in HIV-infected individuals taking TDF and TDF co-formulations.

8.8 Pediatric Use:
The pharmacokinetics of TDF and tenofovir have not been fully studied in the elderly (65 years of age and older). The pharmacokinetics of TDF and tenofovir are altered in subjects with renal impairment (see Warnings and Precautions 6.3). HIV-1 infected subjects with estimated creatinine clearance below 30 mL/min and in individuals with end-stage renal disease requiring dialysis. (See Dosage and Administration 2.6).

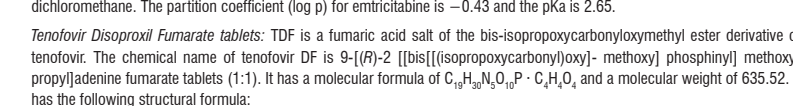
8.9 OVERDOSE:
If overdose occurs, the patient must be monitored for evidence of toxicity, and standard supportive treatment applied as necessary. Emtricitabine hemodialysis treatment removes approximately 90% of the TDF dose over a 3-hour dialysis period starting within 1-2 hours of TDF dosing (about five fold of 400 mL/min and a dialysis flow rate of 600 mL/min). It is not known whether TDF can be removed by peritoneal dialysis.

8.10 Tenofovir Disoproxil Fumarate Tablets: Tenofovir is effectively removed by hemodialysis with an extraction coefficient of approximately 54%. Following a single 300 mg dose of TDF, a three-hour hemodialysis session removed approximately 10% of the administered tenofovir dose.

8.11 Emtricitabine: Emtricitabine and tenofovir disoproxil fumarate tablets are fixed-dose combination tablets containing emtricitabine (FTC) and tenofovir disoproxil fumarate (TDF). TDF is a nucleoside analog of cytosine. TDF is a synthetic nucleoside analog of cytosine. TDF is converted to its active form, tenofovir, an acyclic nucleoside phosphonate (nucleoside analog of adenosine 5'-triphosphate). Both FTC and tenofovir exhibit inhibitory activity against HIV-1 reverse transcriptase.

8.12 Emtricitabine: The chemical name of FTC is 4-Amino-5-bromo-1-(2R,5S)-2-(phospho (methyl-3-oxoimidazo[5,1-b]-2-ylideneamino) ethyl) imidazole. FTC is the 1:1 enantiomer of a 5:5 analog of cytosine, which differs from other cytosine analogs in that it has a fluorine at the 5-position.

It is a nucleoside form of C₁₂H₁₀N₆O₅ and a molecular weight of 281.24. It has the following structural formula:



FTC is a white to almost white crystalline powder and freely soluble in methanol and water, practically insoluble in dichloromethane. The partition coefficient (log P) for emtricitabine is -0.43 and the pKa is 2.26.

8.13 Tenofovir Disoproxil Fumarate Tablets: TDF is a nucleoside analog of cytosine. TDF is converted to its active form, tenofovir, an acyclic nucleoside phosphonate (nucleoside analog of adenosine 5'-triphosphate). Both FTC and tenofovir exhibit inhibitory activity against HIV-1 reverse transcriptase.

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8.68 Emtricitabine: The chemical name of FTC is 4-Amino-5-bromo-1-(2R,5S)-2-(phospho (methyl-3-oxoimidazo[5,1-b]-2-ylideneamino) ethyl) imidazole. FTC is the 1:1 enantiomer of a 5:5 analog of cytosine, which differs from other cytosine analogs in that it has a fluorine at the 5-position.

8.69 Tenofovir Disoproxil Fumarate Tablets: TDF is a nucleoside analog of cytosine. TDF is converted to its active form, tenofovir, an acyclic nucleoside phosphonate (nucleoside analog of adenosine 5'-triphosphate). Both FTC and tenofovir exhibit inhibitory activity against HIV-1 reverse transcriptase.

8.70 Emtricitabine: The chemical name of FTC is 4-Amino-5-bromo-1-(2R,5S)-2-(phospho (methyl-3-oxoimidazo[5,1-b]-2-ylideneamino) ethyl) imidazole. FTC is the 1:1 enantiomer of a 5:5 analog of cytosine, which differs from other cytosine analogs in that it has a fluorine at the 5-position.

8.71 Tenofovir Disoproxil Fumarate Tablets: TDF is a nucleoside analog of cytosine. TDF is converted to its active form, tenofovir, an acyclic nucleoside phosphonate (nucleoside analog of adenosine 5'-triphosphate). Both FTC and tenofovir exhibit inhibitory activity against HIV-1 reverse transcriptase.

8.72 Emtricitabine: The chemical name of FTC is 4-Amino-5-bromo-1-(2R,5S)-2-(phospho (methyl-3-oxoimidazo[5,1-b]-2-ylideneamino) ethyl) imidazole. FTC is the 1:1 enantiomer of a 5:5 analog of cytosine, which differs from other cytos