

Emtifovir®

Emtricitabine 200 mg + Tenofovir Disoproxil Fumarate 300 mg

Presentation
Emtifovir® Tablet: Each tablet contains Emtricitabine INN 200 mg and Tenofovir Disoproxil
Fumarate USP 300 mg.

 $\mathbf{H}\mathbf{H}$

Description
Emtifovir is the combination of Emtricitabine and Tenofovir Disoproxil Fumarate. Tenofovir Disoproxil Fumarate is converted in-vivo to Tenofovir. Emtricitabine and Tenofovir exhibit inhibitory activity against HIV-1 reverse transcriptase enzyme.

- Indication and Uses

 1. Treatment of HIV-1 infection (adults and children over 12 years of age): In combination with
- 2. Pre-Exposure Prophylaxis (adults): In combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 in adults at high risk.

 For pre-exposure prophylaxis the following factors may help to identify individuals at high risk:

 has partner(s) known to be HIV-1 infected, or

- partner(s) of unknown HIV-1 status with any of the factors listed above

- Notes:

 A negative HIV-1 test should immediately be confirmed prior to initiating Emtifovir for a pre-exposure prophylaxis indication.
- Screening for HIV-1 infection should be performed at least once every 3 months while taking Emtifovir for pre-exposure prophylaxis.

- Dosage and Administration
 1. Treatment of HIV-1 infection (adults and children over 12 years of age): One tablet once daily taken orally with or without food.
- 2. Pre-Exposure Prophylaxis (adults): One tablet once daily taken orally with or without food.

Dose adjustment for renal impairment

Treatment of HIV-1 Infection:

	Creatinine Clearance (mL/min)*		
	≥ 50	30-49	< 30 (Including Patients Requiring Hemodialysis)
Recommended Dosing Interval	Every 24 hours	Every 48 hours	should not be administered.
*Coloulated using ideal (lean) hady weight			

Routine monitoring of estimated creatinine clearance, serum phosphorus, urine glucose, and urine protein should be performed in all individuals with mild renal impairment.

Pre-exposure Prophylaxis:

Do not use Emtifovir for a Pre-Exposure Prophylaxis indication in HIV-1 uninfected individuals with estimated creatinine clearance below 60 mL/min.

Side Effect

In HIV-1 infected subjects: The most common adverse reactions include diarrhea, nausea, fatigue, headache, dizziness, depression, insomnia, abnormal dreams, and rash.

In HIV-1 uninfected adult subjects: No new adverse reactions were identified.

- Precautions
 Caution must be exercised when the following adverse reactions occur:

- Severe Acute Exacerbations of hepatitis B:

Severe acute exacerbations of hepatitis B:

Severe acute exacerbations of hepatitis B have been reported in patients who are coinfected with HBV and HIV-1 and have discontinued Emtifovir.

- New Onset or Worsening Renal Impairment
- Immune Reconstitution Syndrome
- Changes in Bone Mineral Density

Use in Pregnancy and Lactation
Pregnancy Category B. Emtifovir has been evaluated in a limited number of women during pregnancy. Emtifovir should be used during pregnancy only if clearly needed.

Emtricitabine and Tenofovir are excreted in human milk. Mothers should be instructed not to breast-feed if they are receiving Emtifovir.

Contraindications

Do not use Emtifovir for pre-exposure prophylaxis in individuals with unknown or positive HIV-1 status. Emtifovir should be used in HIV-infected patients only in combination with other antiretroviral agents.

Drug Interactions
Coadministration of Emtifovir and Didanosine, HIV-1 protease inhibitors or drugs affecting renal function (as Emtifovir is preliminarily excreted through urine) should be undertaken with caution.

Overlose if overdose occurs, the patient must be monitored for evidence of toxicity, and standard supportive treatment applied as necessary.

Commercial pack: Emtifovir® Tablet: Each box contains 2 Alu-Alu blisters of 4 tablets.



EFT