### Pharmacokinetics

**What are the ingredients in Dolutegravir, Lamivudine and Tenofovir Alafenamide Tablets?**

- **Dolutegravir**: 50 mg, 90 mg
- **Lamivudine**: 30 mg, 60 mg
- **Tenofovir Alafenamide**: 25 mg, 50 mg

**Dolutegravir**:
- Once daily, 50 mg
- Twice daily, 90 mg

**Lamivudine**:
- Once daily, 30 mg
- Twice daily, 60 mg

**Tenofovir Alafenamide**:
- Once daily, 25 mg
- Twice daily, 50 mg

**Bioavailability**
- Dolutegravir: 92% after a single 50-mg dose
- Lamivudine: 97% after a single 30-mg dose
- Tenofovir Alafenamide: 51% after a single 50-mg dose

**Cmax and T1/2**
- **Dolutegravir**: Cmax = 1.34 ng/mL, T1/2 = 1.42 hours
- **Lamivudine**: Cmax = 0.97 ng/mL, T1/2 = 0.01 hours (28.5 minutes)
- **Tenofovir Alafenamide**: Cmax = 10 ng/mL, T1/2 = 1.6 hours

**Excretion**
- **Dolutegravir**: 99% excreted unchanged in urine
- **Lamivudine**: 99% excreted unchanged in urine
- **Tenofovir Alafenamide**: 51% excreted unchanged in urine

**Population Pharmacokinetics**
- **HIV-1-infected subjects**: Population pharmacokinetics analysis of TAF with FTC, EVG, and TDF.
- **Pediatric subjects**: Population pharmacokinetics analysis of Dolutegravir and Lamivudine in pediatric subjects.

### Adverse Reactions

**Common adverse reactions**
- Headache
- Back pain, aching, or tenderness on the right side of your stomach area
- Nausea

**Severe adverse reactions**
- Perforation

**Drug Interactions**

- Ethinyl estradiol 0.035 mg
- Prednisone 60 mg once daily
- Fosamprenavir/ritonavir 700 mg/100 mg twice daily
- Etravirine + darunavir/cobicistat
- Lopinavir/ritonavir 700 mg/150 mg twice daily
- Efavirenz, Emtricitabine, Tenofovir disoproxil fumarate

**Special Considerations**

- Use in the elderly
- Use in pregnancy
- Use in breastfeeding

**DrugDosage**

- **Dolutegravir**: 50 mg once daily
- **Lamivudine**: 30 mg once daily
- **Tenofovir Alafenamide**: 25 mg once daily

**Protein Binding**
- **Dolutegravir**: Greater than or equal to 98.9%
- **Lamivudine**: 97%
- **Tenofovir Alafenamide**: 51%

**Folvate Forte**

- **Folvate Forte**: 0.98 mg ethinyl estradiol 0.035 mg
- **Prednisone**: 60 mg once daily
- **Fosamprenavir/ritonavir**: 700 mg/100 mg twice daily
- **Etravirine + darunavir/cobicistat**: 1.91 to 2.33 AUC
- **Lopinavir/ritonavir**: 0.96 to 1.06 increase
- **Efavirenz, Emtricitabine, Tenofovir disoproxil fumarate**: 0.96 to 1.06 increase

**HIV-1 RNA**

- **HIV-1 RNA** decreased to less than 50 copies per mL
- **HIV-1 RNA** decreased to less than 400 copies per mL

**HIV-2**

- **HIV-2** decreased to less than 400 copies per mL

**Drug Interactions**

- **Fosamprenavir/ritonavir**: 0.95 to 1.00 increase
- **Lopinavir/ritonavir**: 0.98 to 1.00 increase
- **Efavirenz, Emtricitabine, Tenofovir disoproxil fumarate**: 0.95 to 1.00 increase

**Carcinogenesis, Mutagenesis, Impairment of Fertility**

- **Carcinogenesis**: No evidence of carcinogenic potential in rats and mice.
- **Mutagenesis**: No evidence of mutagenic potential in mammalian cell assays.
- **Impairment of Fertility**: No evidence of impairment of fertility in rats and mice.

**Revised: 03/2022**