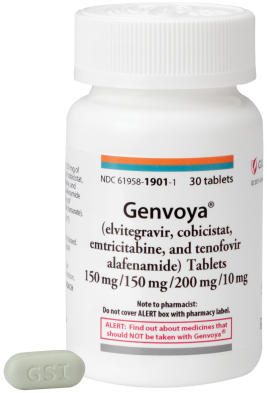
Genvoya

(elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide)



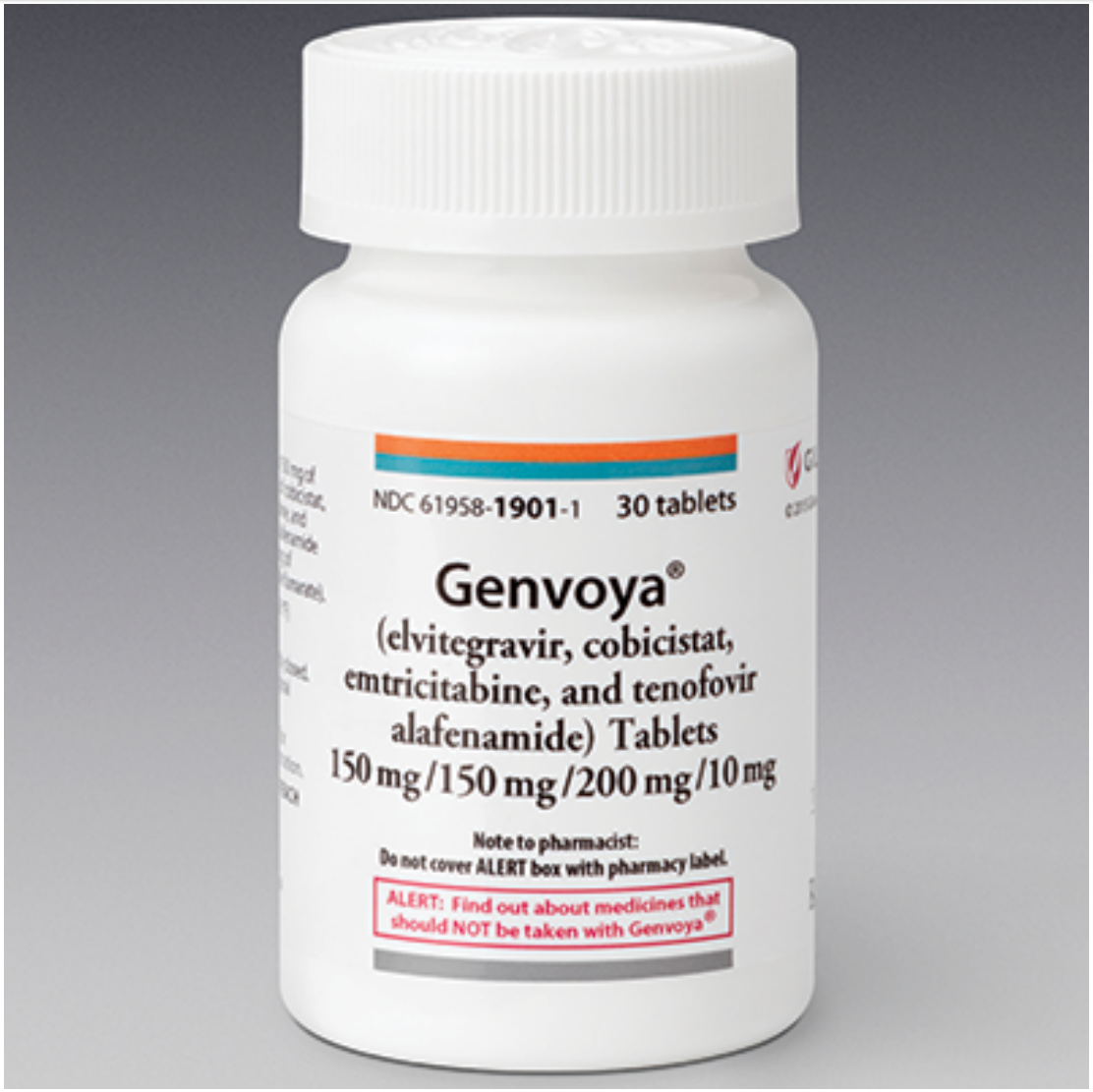
New Product Slideshow

MPR

Introduction

- **Brand name:** Genvoya
- **Generic name:** Elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide (AF)
- **Pharmacological class:** HIV-1 integrase strand transfer inhibitor (INSTI) + pharmacokinetic enhancer + nucleos(t)ide analog reverse transcriptase inhibitors
- **Strength and Formulation:** 150mg/150mg/200mg/10mg; tablets
- **Manufacturer:** Gilead Sciences
- **How supplied:** Bottle—30
- **Legal Classification:** Rx

GENVOYA


NDC 61958-1901-1 30 tablets
Genvoya®
(elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide) Tablets
150 mg/150 mg/200 mg/10 mg
Note to pharmacist:
Do not cover ALERT box with pharmacy label.
ALERT: Find out about medicines that should NOT be taken with Genvoya®

Indications

- As a complete regimen for the treatment of **HIV-1 infection** in patients who are antiretroviral treatment-naïve or to replace current antiretroviral (ARV) regimen in virologically-suppressed patients on a stable ARV regimen for ≥6 months with no history of treatment failure and no known substitutions associated with resistance to any components of Genvoya

Dosage & Administration

- ≥12 years (≥35kg): 1 tab once daily with food
- Severe hepatic or renal impairment (CrCl <30mL/min): not recommended

Considerations for Special Populations

- **Pregnancy:** Pregnancy (Cat. B)
- **Nursing mothers:** Not recommended
- **Pediatric:** <12 years: not established
- **Geriatric:** Insufficient number of patients studied
- **Renal or hepatic impairment:** See Dosage

Contraindications

- Concomitant alfuzosin, carbamazepine, phenobarbital, phenytoin, rifampin, ergots, cisapride, St. John's wort, lovastatin, simvastatin, pimozide, sildenafil (when dosed for PAH), triazolam, oral midazolam

Warnings/Precautions

- **Suspend** therapy if lactic acidosis or hepatotoxicity (eg, hepatomegaly, steatosis) occurs
- Not for treating **chronic hepatitis B**; test for HBV before starting therapy and closely monitor patients co-infected with HBV and HIV for several months after stopping treatment (discontinuing therapy may exacerbate HBV infection)

Warnings/Precautions

- **Monitor** CrCl, urine glucose, urine protein, serum phosphorus (in patients at risk for renal impairment; discontinue if significant renal dysfunction or Fanconi syndrome occurs)
- History of pathologic fracture or risk factors of osteoporosis or bone loss: consider monitoring bone mineral density

Interactions

- See **Contraindications**
- Avoid with concurrent or recent use of nephrotoxic agents
- Do not co-administer with other antiretroviral agents (eg, elvitegravir, cobicistat, emtricitabine, tenofovir DF, lamivudine, adefovir dipivoxil, ritonavir) or antimycobacterials (eg, rifabutin, rifapentine)
- May be potentiated by CYP3A inhibitors, antagonized by CYP3A inducers

Interactions

- May be potentiated by drugs that decrease renal function or compete for active tubular secretion (eg, acyclovir, cidofovir, ganciclovir, valacyclovir, valganciclovir, aminoglycosides, NSAIDs)
- May potentiate drugs metabolized by CYP3A or CYP2D6, or are substrates of P-gp, BCRP, OATP1B1 or OATP1B3
- May antagonize CYP2C9 substrates
- Separate antacids by at least 2 hours

Interactions

- May **potentiate** antiarrhythmics, digoxin, clarithromycin (reduce dose by 50% if CrCl 50–60mL/min), telithromycin, IV midazolam, ethosuximide, SSRIs, TCAs, trazodone, ketoconazole, itraconazole, voriconazole, beta-blockers, calcium channel blockers, fluticasone (use alternatives), atorvastatin, immunosuppressants, neuroleptics, sedatives/hypnotics, PDE5 inhibitors
- Antagonized by oxcarbazepine, systemic dexamethasone; use alternatives
- Concomitant colchicine (see full labeling); avoid in renal or hepatic impairment

Interactions

- Concomitant buprenorphine/naloxone; monitor
- Discontinue bosentan ≥36 hours prior to initiation of Genvoya; resume bosentan after ≥10 days following initiation
- Concomitant salmeterol: not recommended; increased risk of cardiovascular events
- Use alternative non-hormonal methods of contraception
- Monitor INR with warfarin

Adverse Reactions

- Nausea
- Diarrhea
- Fatigue
- Headache
- Decreased BMD
- New onset or worsening renal impairment

Mechanism of Action

- Genvoya is a fixed-dose combination of an HIV-1 INSTI, elvitegravir (boosted by the CYP3A inhibitor cobicistat), and nucleos(t)ide reverse transcriptase inhibitors, emtricitabine and tenofovir alafenamide (TAF)
- TAF is a novel targeted prodrug of tenofovir that has demonstrated high antiviral efficacy similar to and at a dose less than one-tenth that of tenofovir disoproxil fumarate (TDF), as well as improvement in surrogate laboratory markers of renal and bone safety as compared to TDF in clinical trials in combination with other antiretroviral agents

Clinical Trials

- The efficacy and safety of Genvoya were evaluated in three Phase 3 studies in which the single tablet regimen met its primary objective of non-inferiority compared to Stribild (Studies 104 and 111) and non-inferior to TDF-based regimens (Study 109)
- Two additional Phase 3 studies of Genvoya among patients with renal impairment (Study 112) and adolescents aged 12−18 years (Study 106) supported the FDA approval

New Product Monograph

- For more information view the complete product monograph available at:

  http://www.empr.com/genvoya/drugproduct/394/