Descovy

(emtricitabine, tenofovir alafenamide)

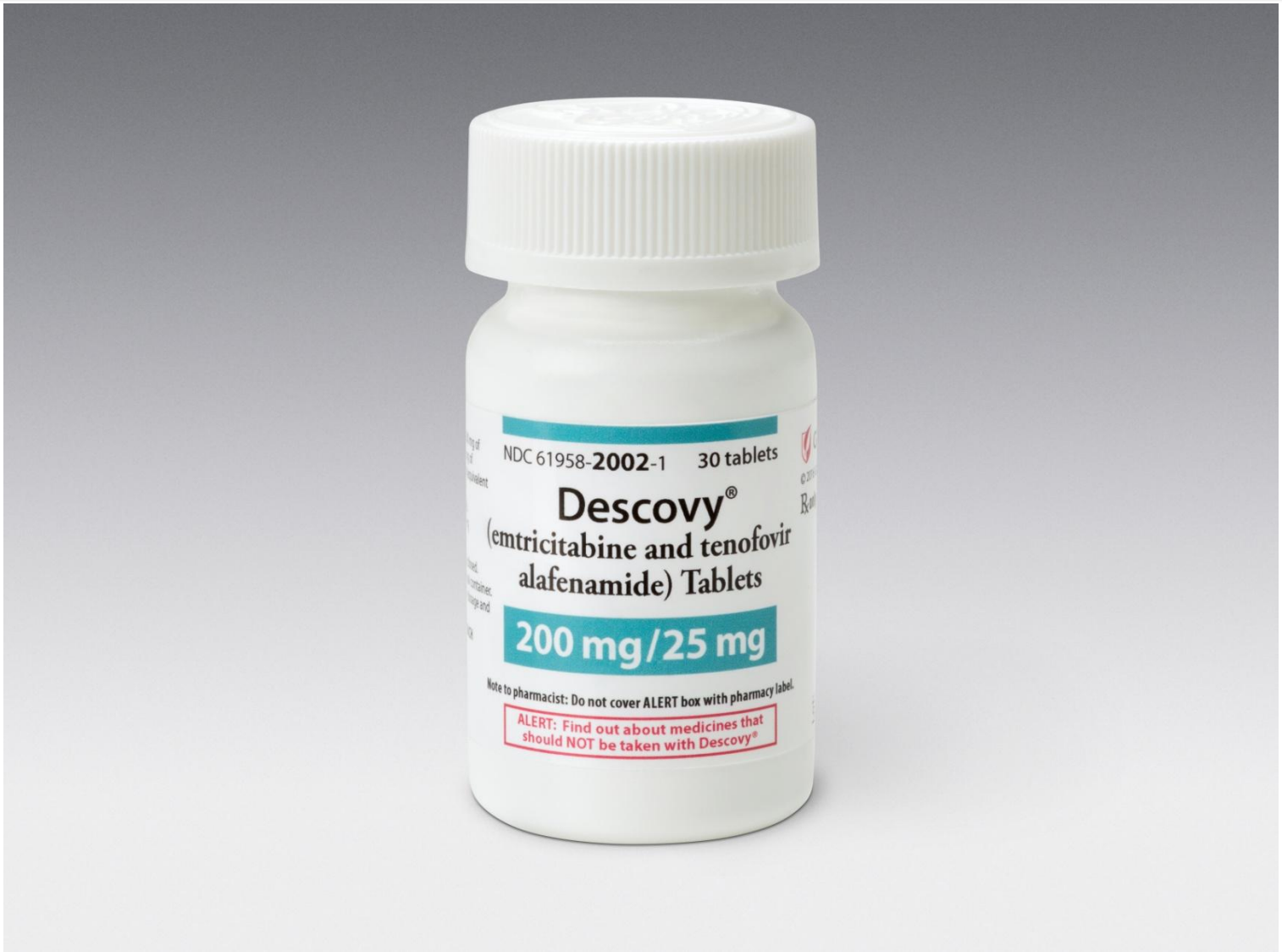
New Product
Slideshow

MPR

Introduction

- **Brand name:** Descovy
- **Generic name:** Emtricitabine, tenofovir alafenamide (TAF)
- **Pharmacological class:** Nucleoside analog reverse transcriptase inhibitors
- **Strength and Formulation:** 200mg/25mg; tablets
- **Manufacturer:** Gilead Sciences
- **How supplied:** Bottle—30
- **Legal Classification:** Rx

DESCOVY


NDC 61958-2002-1 30 tablets
Descovy®
(emtricitabine and tenofovir alafenamide) Tablets
200 mg/25 mg
Note to pharmacist: Do not cover ALERT box with pharmacy label.
ALERT: Find out about medicines that should NOT be taken with Descovy®

Indications

- HIV-1 infection, in combination with other antiretroviral agents
- **Limitations of use:** Not for use as pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV in high-risk adults

Dosage & Administration

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

Considerations for Special Populations

- **Pregnancy:** Insufficient human data
- **Nursing mothers:** Not recommended
- **Pediatric:** <12yrs (<35kg): not established
- **Geriatric:** No differences in safety or efficacy
- **Renal impairment:** Severe impairment (CrCl <30mL/min): not recommended
- **Hepatic impairment:** Severe impairment: not studied

Warnings/Precautions

- **Suspend** therapy if lactic acidosis or hepatotoxicity (eg, hepatomegaly, steatosis) occurs
- Not for treating **chronic hepatitis B virus** (HBV); 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)
- If appropriate, initiation of anti-hepatitis B therapy may be warranted (especially in those with advanced liver disease or cirrhosis)

Warnings/Precautions

- **Monitor** CrCl, urine glucose, urine protein, serum phosphorus in patients at risk for chronic renal disease; **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 (BMD); calcium/vitamin D supplement may be beneficial

Interactions

- Concomitant drugs that strongly affect P-glycoprotein activity may lead to changes in TAF absorption
- **Avoid** with concurrent or recent use of nephrotoxic agents
- Concomitant tipranavir/ritonavir, antimycobacterials (eg, rifabutin, rifampin, rifapentine), St. John's wort: **not recommended**

Interactions

- May be **antagonized** by anticonvulsants (eg, carbamazepine, oxcarbazepine, phenobarbital, phenytoin; consider alternatives
- May be **potentiated** by drugs that decrease renal function or compete for active tubular secretion (eg, acyclovir, cidofovir, ganciclovir, valacyclovir, valganciclovir, aminoglycosides, NSAIDs)

Adverse Reactions

- Nausea
- New onset or worsening renal impairment
- Fat redistribution
- Immune reconstitution syndrome
- Decreased bone mineral density

Note

- Register pregnant patients in the Antiretroviral Pregnancy Registry (APR) by calling (800) 258-4263

Mechanism of Action

- Descovy is a fixed-dose combination of antiretroviral drugs emtricitabine and tenofovir alafenamide
- **Emtricitabine** is phosphorylated by cellular enzymes to form emtricitabine 5'-triphosphate, which inhibits the activity of the HIV-1 reverse transcriptase by competing with the natural substrate deoxycytidine 5'-triphosphate and by being incorporated into nascent viral DNA, which results in chain termination

Mechanism of Action

- **Tenofovir alafenamide**, a phosphonoamidate prodrug of tenofovir, is intracellularly converted through hydrolysis
- Its active metabolite, tenofovir diphosphate, inhibits HIV-1 replication through incorporation into viral DNA by the HIV reverse transcriptase, which results in chain termination

Clinical Trials

- In trials of FTC+TAF with elvitegravir + cobicistat (EVG+COBI) in HIV-1 infected adults as initial therapy in those with no treatment history (N=866), and to replace a stable antiretroviral regimen in those who were virologically-suppressed for ≥6 months with no known resistance substitutions (N=799), **92%** and **96%** of patients, respectively, had HIV-1 RNA <50 copies/mL at Week 48

Clinical Trials

- In a trial of FTC+TAF with EVG+COBI in treatment-naïve HIV-1 infected pediatric patients (N=23), the virologic response rate was **91%** at Week 24

Clinical Trials

- In a trial with HIV-1 infected adults with CrCl 30−<70mL/min (N=248), **95%** of the combined population of treatment-naive subjects (N=6) began FTC+TAF with EVG+COBI and those previously virologically-suppressed on other regimens (N=242) and switched to FTC +TAF with EVG+COBI had HIV-1 RNA <50 copies/mL at Week 24
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/descovy/drug/34545/