RXADVANCE
2 Park Central Drive
Southborough, MA 01772

FIRST TIME GENERIC APPROVAL

Brand Name	Atripla®
Generic Name	efavirenz-emtricitabin-tenofovir disoproxil fumarate
Drug Manufacturer	Teva Pharmaceuticals USA

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic Approval

FDA APPROVAL DATE

November 9, 2018

LAUNCH DATE

October 2, 2020

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 091215

DISPENSING RESTRICTIONS

Open Distribution

Overview

INDICATION FOR USE

Efavirenz, emtricitabine, and tenofovir disoproxil fumarate is a three-drug combination of efavirenz (EFV), a nonnucleoside reverse transcriptase inhibitor, and emtricitabine (FTC) and tenofovir disoproxil fumarate (TDF), both HIV-1 nucleoside analog reverse transcriptase inhibitors, and is indicated as a complete regimen or in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 40 kg.

MECHANISMS OF ACTION

Efavirenz-lamivudine-tenofovir disoproxil fumarate is a fixed-dose combination of antiviral drugs EFV, 3TC, and TDF with antiviral activity against HIV-1.

Efavirenz: EFV is an NNRTI of HIV-1. EFV activity is mediated predominantly by non-competitive inhibition of HIV-1 reverse transcriptase (RT). HIV-2 RT and human cellular DNA polymerases α, β, γ, and δ are not inhibited by EFV.

Emtricitabine: A synthetic nucleoside analog of cytidine, is phosphorylated by cellular enzymes to form emtricitabine 5'-triphosphate. Emtricitabine 5'-triphosphate inhibits the activity of the HIV-1 RT by competing with the natural substrate deoxycytidine 5'-triphosphate and by being incorporated into nascent viral DNA which results in chain termination. Emtricitabine 5’-triphosphate is a weak inhibitor of mammalian DNA polymerase α, β, ε, and mitochondrial DNA polymerase γ.

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Tenofovir Disoproxil Fumarate: TDF is an acyclic nucleoside phosphonate diester analog of adenosine monophosphate. TDF requires initial diester hydrolysis for conversion to tenofovir and subsequent phosphorylations by cellular enzymes to form tenofovir diphosphate (TDF-DP), an obligate chain terminator. Tenofovir diphosphate inhibits the activity of HIV-1 reverse transcriptase (RT) and HBV RT by competing with the natural substrate deoxyadenosine 5'-triphosphate and, after incorporation into DNA, by DNA chain termination. Tenofovir diphosphate is a weak inhibitor of mammalian DNA polymerases α, β, and mitochondrial DNA polymerase γ.

DOSE FORM AND STRENGTH

Tablets: 600 mg efavirenz, 200 mg emtricitabine and 300 mg tenofovir disoproxil fumarate (equivalent to 245 mg of tenofovir disoproxil)

DOSE & ADMINISTRATION

1 tablet (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) orally once daily on empty stomach at bedtime