

FIRST TIME GENERIC APPROVAL

Brand Name	Symfi™, Symfi Lo™
Generic Name	efavirenz-lamivu-tenofov disoproxil fumarate
Drug Manufacturer	Laurus Labs Limited

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic Approval

FDA APPROVAL DATE

May 14, 2020

LAUNCH DATE

N/A

REVIEW DESIGNATION

N/A

TYPE OF REVIEW

Standard

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

A complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 35 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.

Lamivudine

3TC is a synthetic nucleoside analog with activity against HIV-1 and HBV. Intracellularly, 3TC is phosphorylated to its active 5'-triphosphate metabolite, lamivudine triphosphate (3TC-TP). The principal mode of action of 3TC-TP is inhibition of HIV-1 reverse transcriptase (RT) via DNA chain termination after incorporation of the nucleotide analog.

Tenofovir Disoproxil Fumarate

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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, 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate (equivalent to 245 mg of tenofovir disoproxil), 400 mg efavirenz, 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate (equivalent to 245 mg of tenofovir disoproxil)

DOSE & ADMINISTRATION

Weight 35 kg or more: efavirenz 400 mg, lamivudine 300 mg, tenofovir disoproxil fumarate 300 mg. Take 1 tablet by mouth on an empty stomach daily.

Weight 40 kg or more: efavirenz 600 mg, lamivudine 300 mg, tenofovir disoproxil fumarate 300 mg. Take 1 tablet by mouth on an empty stomach daily.

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