FIRST TIME GENERIC APPROVAL

Brand Name	Etravirine
Generic Name	etravirine
Drug Manufacturer	Amneal Pharmaceuticals

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

June 14, 2021

LAUNCH DATE

N/A

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 214196

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Etravirine is a human immunodeficiency virus type 1 (HIV-1) non-nucleoside reverse transcriptase inhibitor (NNRTI) indicated for treatment of HIV-1 infection in treatment-experienced patients 6 years of age and older.

MECHANISMS OF ACTION

Etravirine is an NNRTI of HIV-1. Etravirine binds directly to reverse transcriptase (RT) and blocks the RNA-dependent and DNA-dependent DNA polymerase activities by causing a disruption of the enzyme's catalytic site. Etravirine does not inhibit the human DNA polymerases α, β, and γ.

DOSE FORM AND STRENGTH

Tablets: 25 mg, 100 mg, and 200 mg

DOSE & ADMINISTRATION

- Adult patients: 200 mg (one 200 mg tablet or two 100 mg tablets) taken twice daily following a meal.
- Pregnant patients: 200 mg (one 200 mg tablet or two 100 mg tablets) taken twice daily following a meal.
- Pediatric patients (6 years to less than 18 years of age and weighing at least 16 kg): dosage of etravirine tablets are based on body weight and should not exceed the recommended adult dose. Etravirine tablets should be taken following a meal.

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