

### HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ENTRICITABINE, NIPRIPIRINE and TENOVIFOR DISPROXIL FUMARATE TABLETS safely and effectively. See full prescribing information for ENTRICITABINE, NIPRIPIRINE and TENOVIFOR DISPROXIL FUMARATE TABLETS.

**ENTRITABINE, NIPRIPIRINE and TENOVIFOR DISPROXIL FUMARATE TABLETS, for oral use**  
Initial U.S. Approval: 2011

**WARNING: POSTTREATMENT ACUTE EXACERBATION OF HEPATITIS B**  
See full prescribing information for complete boxed warning.

**Severe acute exacerbations of hepatitis B virus (HBV) have been reported in patients coinfected with HIV-1 and HBV who have discontinued products containing entricitabine (FTC) and/or tenovifor disproxil fumarate (TDF). In patients with HIV-1 infection, entricitabine, nipiipirine and tenovifor disproxil fumarate tablets. Closely monitor hepatic function with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue entricitabine, nipiipirine and tenovifor disproxil fumarate tablets, if appropriate. Initiation of anti-hepatitis B therapy may be warranted. (5.1)**

**INDICATIONS AND USAGE**  
Entricitabine, nipiipirine and tenovifor disproxil fumarate tablets, a combination of two nucleoside analogs (FTC and TDF), are indicated for the treatment of HIV-1 infection in patients who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) and who are not receiving antiretroviral therapy with a non-nucleoside reverse transcriptase inhibitor (NNRTI), as indicated for use as a complete regimen for the treatment of HIV-1 infection in patients weighing at least 35 kg (1) as initial therapy or in combination with other antiretroviral drugs in patients weighing at least 50 kg (1), 100,000 copies/mL, at the start of therapy, or (2) or to re-initiate antiretroviral therapy in those who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) for at least 6 months with no treatment failure and to know no substitution associated with resistance to the individual components of entricitabine, nipiipirine and tenovifor disproxil fumarate tablets. (1, 14)

**Limitations of Use**  
More HIV-1-positive treated subjects with HIV-1 RNA greater than 100,000 copies/mL at 14 weeks of therapy experienced virologic failure (HIV-1 RNA  $\geq 100,000$  copies/mL) compared to HIV-1-negative treated subjects with HIV-1 RNA less than or equal to 100,000 copies/mL. (1, 14)

**DOSE AND ADMINISTRATION**  
Testing: Prior to or during treatment with entricitabine, nipiipirine and tenovifor disproxil fumarate tablets, test for hepatitis B virus infection. Prior to initiation and during treatment with entricitabine, nipiipirine and tenovifor disproxil fumarate tablets, on a clinically appropriate schedule, assess serum creatinine, estimated creatinine clearance, urine glucose, and urine protein in all patients. In patients with chronic kidney disease, also assess serum phosphorus. (2, 3)

**Pharmacokinetic Studies in Adults and Pediatric Patients Weighing at Least 35 kg**  
One tablet taken orally once daily with food. (2)

**Renal Impairment**  
Not recommended in patients with estimated creatinine clearance below 50 mL per minute. (2, 4)

**Recommended Dosage with Ribavirin Coadministration**  
An additional 25 mg tablet of ribavirin (Eduard) once per day taken concomitantly with entricitabine, nipiipirine and tenovifor disproxil fumarate tablets and with a reduced dose of ribavirin coadministration. (2, 3, 7, 12, 13)

**DOSE FORMS AND STRENGTHS**  
Tablets: 200 mg of entricitabine, 25 mg of nipiipirine, and 300 mg of tenovifor disproxil fumarate. (3)

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**PATENT/COPYRIGHT INFORMATION**  
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### CONTRAINDICATIONS

Entricitabine, nipiipirine and tenovifor disproxil fumarate tablets are contraindicated when administered with drugs which may result in loss of virologic response and possible resistance to entricitabine, nipiipirine and tenovifor disproxil fumarate tablets. (5)

**WARNINGS AND PRECAUTIONS**  
Skin and Hypersensitivity Reactions: Severe skin and hypersensitivity reactions have been reported during postmarketing experience, including cases of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) with associated fever, rash, eosinophilia, and lymphopenia with systemic symptoms or elevations in hepatic serum biochemistries develops and acute renal failure. (5.2)

Hepatitis: Hepatic adverse events have been reported in patients receiving a nipiipirine-containing regimen. Monitor liver-associated tests during treatment with entricitabine, nipiipirine and tenovifor disproxil fumarate tablets. (5.3)

Depressive Disorders: Severe depressive disorders have been reported. Immediate medical attention is recommended for severe depressive disorders. (5.4)

Immune Reconstitution Syndrome: Immune reconstitution syndrome may occur in patients with HIV-1 infection. (5.3)

Severe Acute Exacerbation of Hepatitis B in Patients Coinfected with HIV-1 and HBV: Severe acute exacerbations of hepatitis B virus (HBV) have been reported in patients coinfected with HIV-1 and HBV who have discontinued products containing entricitabine (FTC) and/or tenovifor disproxil fumarate (TDF). (5.1)

Pregnancy: Monitor viral load closely during pregnancy as nipiipirine exposures were generally lower during pregnancy. (8.1)

Lactation: Breastfeeding not recommended due to the potential for HIV transmission. (8.2)

Pediatric Use: Not recommended for patients weighing less than 35 kg. (8.4)

Renal Impairment: Not recommended in patients with estimated creatinine clearance below 50 mL per minute. (8.6)

Hepatic Impairment: Not recommended in patients with estimated creatinine clearance below 50 mL per minute. (8.7)

Drug Interactions: Not recommended with other antiretroviral medications. (7.1)

Other Laboratory Test Interactions: Test for hepatitis B virus infection. (2.1)

Other Laboratory Test Interactions: Monitor liver-associated tests during treatment with entricitabine, nipiipirine and tenovifor disproxil fumarate tablets. (5.3)

Other Laboratory Test Interactions: Monitor renal function. (2.2)

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### ADVERSE REACTIONS

Severe depressive disorders have been reported. Immediate medical attention is recommended for severe depressive disorders. (5.4)

Immune reconstitution syndrome may occur in patients with HIV-1 infection. (5.3)

Severe acute exacerbations of hepatitis B virus (HBV) have been reported in patients coinfected with HIV-1 and HBV who have discontinued products containing entricitabine (FTC) and/or tenovifor disproxil fumarate (TDF). (5.1)

Monitor liver-associated tests during treatment with entricitabine, nipiipirine and tenovifor disproxil fumarate tablets. (5.3)

Monitor renal function. (2.2)

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### DRUG INTERACTIONS

Not recommended with other antiretroviral medications. (7.1)

Test for hepatitis B virus infection. (2.1)

Monitor liver-associated tests during treatment with entricitabine, nipiipirine and tenovifor disproxil fumarate tablets. (5.3)

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### HOW SUPPLIED/STORAGE AND HANDLING

Tablets: 200 mg of entricitabine, 25 mg of nipiipirine, and 300 mg of tenovifor disproxil fumarate. (3)

Storage: Store at controlled room temperature. (3)

Stability: Stable for 30 months. (3)

Excipients: Contains inactive ingredients. (3)

Other Information: See full prescribing information for complete information. (3)

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**PRODUCT DETAILS**

TYPE OF REQUEST	New
PRODUCT NAME	Emtricitabine, Rilpivirine and Tenofovir Disoproxil Fumarate Tablets 200 mg/25 mg/300 mg
BRAND NAME	NA
GENERIC NAME	Emtricitabine, Rilpivirine and Tenofovir Disoproxil Fumarate Tablets 200 mg/25 mg/300 mg
STRENGTH	200 mg/25 mg/300 mg
DOSAGE FORM	Tablets
PACK SIZE	30's
PACK STYLE	Bottle Pack
MARKETS	US
COUNTRY	United States of America
LANGUAGE	English
CUSTOMER APPROVAL REQUIRED	No
PRODUCT TYPE	Own Product
CUSTOMER	Not entered
WORKFLOW	Laurus-AMS-Own Product Process-New
TYPE OF PRODUCT	First release
FG CODE	7001954
FG CODE DESCRIPTION	Emtricitabine, Rilpivirine and Tenofovir Disoproxil Fumarate Tablets 200 mg/25 mg/300 mg, Bottle 30's - US
SPECIAL INSTRUCTIONS	Not entered
REMARKS	CC-V2-25-0600

**MATERIAL DETAILS**

PHARMA CODE	1936
BARCODE	NA
COMPONENT DETAILS	Leaflet(Printed)
NEW MATERIAL CODE	2004086
OLD MATERIAL CODE	Not entered

**CHANGE REQUEST DETAILS**

APPROVED DATE	Not entered
REASON FOR CHANGE/INITIATION	Not entered
CHANGE CONTROL NUMBER	Not entered
REMARKS	Not entered

**Finalization Summary**

ACTION BY	DEPARTMENT	ACTION	ACTION ON	COMMENTS
11754-Swathi Kasireddy	Packaging Development	Initiate	23-09-2025 12:14:00	Artwork Initiated
11754-Swathi Kasireddy	Packaging Development	Artwork Upload	23-09-2025 12:40:51	Artwork Submitted
7853-Satyanarayana Sastry Nandula	Packaging Development	Checklist Review	23-09-2025 13:25:28	Artwork approved
12709-Bhuvana Kantipudi	Regulatory Affairs	Checklist Review	24-09-2025 10:48:55	yes. The product is still under FDA review. Hence proceed up to print proof stage.
9354-Sai Keerthi Bammidi	Quality Assurance	Artwork Finalisation	24-09-2025 17:04:01	Artwork is approved

Approved