

Your Emtricitabine and Tenofovir Disoproxil Fumarate Tablets Savings Card

teva | emtricitabine and tenofovir
disoproxil fumarate
tablets 200mg/300mg

Pay as
little as
\$0

Expires: **3/29/2021**

BIN **600426**

GRP **EC74032001**

PCN **54**

ID **49581288850**

You must present this offer and your primary insurance card to the pharmacist along with your prescription. This offer is not available to non-insured/cash-paying patients, nor to patients eligible for prescription coverage by any state or federally funded healthcare programs. See full Terms and Conditions.

SAVINGS OFFER TERMS, CONDITIONS, AND ELIGIBILITY REQUIREMENTS

Terms and Conditions: Patients are not eligible if prescriptions are paid for in part or full by any state or federally funded programs, including but not limited to Medicare, Medicaid, Medigap, VA, DOD, TRICARE, or by private health benefit programs which reimburse for the entire cost of prescription drugs. This card is not valid for patients who are Medicare eligible and are enrolled in an employer-sponsored health plan or prescription drug benefit program for retirees (i.e., patients who are eligible for Medicare Part D but who receive a prescription drug benefit through a former employer). Cash Discount Cards and other non-insurance plans are not valid as primary under this offer. If the patient is eligible for drug benefits under any such program, the patient cannot use this offer. By redeeming this offer, the patient and the pharmacist attest that the patient is eligible, and the patient and the pharmacist understand and agree to comply with the Terms and Conditions of this offer.

Void if copied, transferred, purchased, altered, or traded and where prohibited and restricted by law. This is not an insurance program. This offer may not be used with any other discount, coupon, or offer. **This offer expires on 3/29/2021. This program is managed by ConnectiveRx on behalf of Teva Pharmaceuticals USA, Inc. Teva reserves the right to limit, change, or discontinue this offer at any time without notice.** If you have any questions regarding your eligibility or benefits, please call 833-330-0807.

Valid only for Teva's Emtricitabine and Tenofovir Disoproxil Fumarate Tablets, 200 mg/300 mg, National Drug Code #00093-7607-56

To the Patient: This offer is for eligible **Commercially Insured Patients only.** Patients pay as little as \$0 out-of-pocket for Teva's Emtricitabine and Tenofovir Disoproxil Fumarate Tablets, with a maximum benefit of \$600 per 28-day supply. Maximum annual benefits apply and out of pocket expenses may vary. Patient is responsible for costs above maximum benefit amounts. This offer must be presented along with your prescription for Emtricitabine and Tenofovir Disoproxil Fumarate Tablets and your primary insurance card to participate in this program. **Offer not valid for Non-Insured/Cash-Paying patients or where Emtricitabine and Tenofovir Disoproxil Fumarate Tablets is not covered by the primary insurance.**

To the Pharmacist: By redeeming this offer, the Pharmacist certifies that Teva's Emtricitabine and Tenofovir Disoproxil Fumarate Tablets is being dispensed to a patient eligible for this offer in compliance with these Terms and Conditions and that the Pharmacy has not submitted and will not submit a claim for reimbursement under any federal, state, or other governmental program for this prescription. For Commercially-Insured Patients: Please submit this claim to the primary Payer first, then submit the balance due to CHANGE HEALTHCARE as a Secondary Payer COB (coordination of benefits) with patient responsibility and a valid Other Coverage Code (e.g. 8). Reimbursement will be received from CHANGE HEALTHCARE. For questions about processing, please call 800-433-4893.

Please see accompanying full Prescribing Information, including Boxed Warning and Medication Guide.

If you tell your healthcare provider before taking emtricitabine and tenofovir disoproxil fumarate tablets? Before taking emtricitabine and tenofovir disoproxil fumarate tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems, including HBV infection
- have kidney problems or receive kidney dialysis treatment
- have bone problems
- are pregnant or plan to become pregnant. It is not known if emtricitabine and tenofovir disoproxil fumarate can harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with emtricitabine and tenofovir disoproxil fumarate tablets.

Pregnancy Registry: There is a pregnancy registry for people who take emtricitabine and tenofovir disoproxil fumarate tablets during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk with your healthcare provider about how you can take part in this registry.

- are breastfeeding or plan to breastfeed. Emtricitabine and tenofovir disoproxil fumarate can pass to your baby in your breast milk.
- Do not breastfeed if you have HIV-1 or if you think you have recently become infected with HIV-1 because of the risk of passing HIV-1 to your baby.
- If you take emtricitabine and tenofovir disoproxil fumarate tablets for HIV-1 PrEP, talk with your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines may interact with emtricitabine and tenofovir disoproxil fumarate tablets. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

You can ask your healthcare provider or pharmacist for a list of medicines that interact with emtricitabine and tenofovir disoproxil fumarate tablets.

- Do not start a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take emtricitabine and tenofovir disoproxil fumarate tablets with other medicines.

How should I take emtricitabine and tenofovir disoproxil fumarate tablets?

- Take emtricitabine and tenofovir disoproxil fumarate tablets exactly as your healthcare provider tells you to take it.
- If you take emtricitabine and tenofovir disoproxil fumarate tablets to treat HIV-1 infection, you need to take other HIV-1 medicines. Your healthcare provider will tell you what medicines to take and how to take them.
- Take emtricitabine and tenofovir disoproxil fumarate tablets 1 time each day with or without food.
- Children who take emtricitabine and tenofovir disoproxil fumarate tablets are prescribed a lower strength tablet than adults. Children should swallow the emtricitabine and tenofovir disoproxil fumarate tablet. Tell your healthcare provider if your child cannot swallow the tablet, because they may need a different HIV-1 medicine.
- Your healthcare provider will change the dose of emtricitabine and tenofovir disoproxil fumarate tablets as needed based on your child's weight.

- Do not change your dose or stop taking emtricitabine and tenofovir disoproxil fumarate tablets without first talking with your healthcare provider. Stay under a healthcare provider's care when taking emtricitabine and tenofovir disoproxil fumarate tablets. Do not miss a dose of emtricitabine and tenofovir disoproxil fumarate tablets.
- If you take too many emtricitabine and tenofovir disoproxil fumarate tablets, call your healthcare provider or go to the nearest hospital emergency room right away.
- When your emtricitabine and tenofovir disoproxil fumarate tablets supply starts to run low, get more from your healthcare provider or pharmacy.

- If you are taking emtricitabine and tenofovir disoproxil fumarate tablets for treatment of HIV-1, the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus will develop resistance to emtricitabine and tenofovir disoproxil fumarate tablets and become harder to treat.
- If you take too many emtricitabine and tenofovir disoproxil fumarate tablets, call your healthcare provider or go to the nearest hospital emergency room right away.
- When your emtricitabine and tenofovir disoproxil fumarate tablets supply starts to run low, get more from your healthcare provider or pharmacy.

- If you are taking emtricitabine and tenofovir disoproxil fumarate tablets for treatment of HIV-1, the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus will develop resistance to emtricitabine and tenofovir disoproxil fumarate tablets and become harder to treat.
- If you take too many emtricitabine and tenofovir disoproxil fumarate tablets, call your healthcare provider or go to the nearest hospital emergency room right away.
- When your emtricitabine and tenofovir disoproxil fumarate tablets supply starts to run low, get more from your healthcare provider or pharmacy.

What are the possible side effects of emtricitabine and tenofovir disoproxil fumarate tablets? Emtricitabine and tenofovir disoproxil fumarate tablets may cause serious side effects, including:

- **New "What is the most important information I should know about emtricitabine and tenofovir disoproxil fumarate tablets?"**
- **See or worse kidney problems, including kidney failure.** Your healthcare provider should do blood and urine tests to check your kidneys before you start and during treatment with emtricitabine and tenofovir disoproxil fumarate tablets. Your healthcare provider may tell you to take emtricitabine and tenofovir disoproxil fumarate tablets less often, or to stop taking emtricitabine and tenofovir disoproxil fumarate tablets if you get new or worse kidney problems.

- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when taking medicines to treat HIV-1 infection. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having any new symptoms after starting your HIV-1 medicine.

- **Bone problems** can happen in some people who take emtricitabine and tenofovir disoproxil fumarate tablets. Bone problems include bone pain, or softening or thinning of bones, which may lead to fractures. Your healthcare provider may need to do tests to check your bones.

- **Too much lactic acid in your blood (lactic acidosis).** Too much lactic acid is a serious but rare medical emergency that can lead to death. Tell your healthcare provider right away if you get these symptoms: weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, stomach pain with nausea and vomiting, cold or blue hands and feet, feel dizzy or lightheaded, or a fast or abnormal heartbeat.

- **Severe liver problems.** In rare cases, severe liver problems can happen that can lead to death. Tell your healthcare provider right away if you get these symptoms: skin or the white part of your eyes turns yellow, dark "tea-colored" urine, light-colored stools, loss of appetite for several days or longer, nausea, or stomach-ache pain.

The most common side effects of emtricitabine and tenofovir disoproxil fumarate tablets for treatment of HIV-1 include:

- diarrhea
- depression
- nausea
- problems sleeping
- tiredness
- abnormal dreams
- headache
- rash
- dizziness

Common side effects in people who take emtricitabine and tenofovir disoproxil fumarate tablets for HIV-1 PrEP include:

- headache
- stomach-ache (abdomen) pain
- decreased weight

These are not all the possible side effects of emtricitabine and tenofovir disoproxil fumarate tablets.

How should I store emtricitabine and tenofovir disoproxil fumarate tablets?

- Store emtricitabine and tenofovir disoproxil fumarate tablets at room temperature between 68° to 77°F (20° to 25°C).
- Keep emtricitabine and tenofovir disoproxil fumarate tablets in their original container.
- Keep the container tightly closed.
- Do not use emtricitabine and tenofovir disoproxil fumarate tablets if seal over bottle opening is broken or missing.

Keep emtricitabine and tenofovir disoproxil fumarate tablets and all other medicines out of reach of children. General information about emtricitabine and tenofovir disoproxil fumarate tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use emtricitabine and tenofovir disoproxil fumarate tablets for a condition for which they were not prescribed. Do not give emtricitabine and tenofovir disoproxil fumarate tablets to other people, even if they have the same symptoms you have. They may harm them. You can ask your healthcare provider or pharmacist for information about emtricitabine and tenofovir disoproxil fumarate tablets that is written for health professionals.

What are the ingredients in emtricitabine and tenofovir disoproxil fumarate tablets? Active ingredients: emtricitabine and tenofovir disoproxil fumarate. Inactive ingredients: croscopolone, F0Dc blue #2 aluminum lake, lactose monohydrate, magnesium stearate, mannitol, polyethylene glycol, polyvinyl alcohol, povidone, talc, and titanium dioxide.

a. All interaction trials conducted in healthy volunteers. b. 1 = Increase; -- = No Effect; NA = Not Applicable

Table 10 Drug Interactions: Changes in Pharmacokinetic Parameters for Coadministered Drug in the Presence of FTC^a

Table 10 Drug Interactions: Changes in Pharmacokinetic Parameters for Coadministered Drug in the Presence of FTC^a

Table 10 Drug Interactions: Changes in Pharmacokinetic Parameters for Coadministered Drug in the Presence of FTC^a

Table 10 Drug Interactions: Changes in Pharmacokinetic Parameters for Coadministered Drug in the Presence of FTC^a

Table 10 Drug Interactions: Changes in Pharmacokinetic Parameters for Coadministered Drug in the Presence of FTC^a

It has the following structural formula:

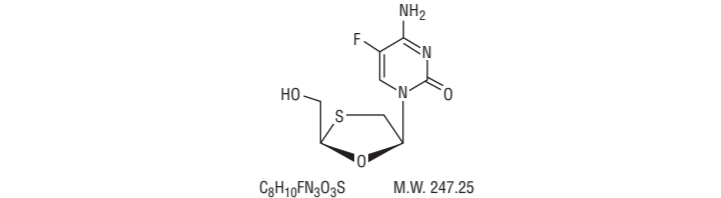


Table 11 Drug Interactions: Changes in Pharmacokinetic Parameters for Tenofovir in the Presence of the Coadministered Drug

Coadministered Drug	Dose of Coadministered Drug (mg)	N	% Change of Tenofovir Pharmacokinetic Parameters ^b (90% CI)		
			C _{max}	AUC	t _{1/2}
Atazanavir ^c	400 once daily x 14 days	33	1.14 (1.8 to 2.0)	1.24 (1.21 to 1.28)	1.22 (1.15 to 1.30)
Atazanavir/ Ritonavir ^c	300/100 once daily	12	1.34 (1.20 to 1.51)	1.30 (1.45)	1.36 (1.21 to 1.36)
Darunavir/ Ritonavir ^d	300/100 twice daily	12	1.24 (1.8 to 1.42)	1.22 (1.10 to 1.35)	1.37 (1.19 to 1.57)
Indinavir	800 three times daily x 7 days	13	1.14 (1.31 to 1.33)	--	--
Ledipasvir/ Sofosbuvir ^{e,1}	90/400 once daily x 10 days	24	1.47 (1.37 to 1.58)	1.35 (1.29 to 1.42)	1.47 (1.38 to 1.57)
Ledipasvir/ Sofosbuvir ^{e,2}	90/400 once daily x 14 days	23	1.54 (1.47 to 1.64)	1.59 (1.42 to 1.59)	1.59 (1.49 to 1.70)
Ledipasvir/ Sofosbuvir ^{e,3}	90/400 once daily x 14 days	15	1.73 (1.56 to 1.04)	1.78 (1.78 to 1.23)	1.63 (1.32 to 1.97)
Ledipasvir/ Sofosbuvir ^e	90/400 once daily x 14 days	14	1.32 (1.25 to 1.39)	1.31 (1.50)	1.91 (1.74 to 1.110)
Ledipasvir/ Sofosbuvir ^e	90/400 once daily x 10 days	29	1.61 (1.51 to 1.72)	1.65 (1.59 to 1.71)	1.15 (1.05 to 1.28)
Lopinavir/ Ritonavir	400/100 twice daily x 14 days	24	1.17 (1.12 to 1.25)	1.32 (1.38)	1.51 (1.37 to 1.66)
Saquinavir/ Ritonavir	1000/100 twice daily x 14 days	35	--	--	1.23 (1.16 to 1.30)
Sofosbuvir ^c	400 single dose	16	1.25 (1.8 to 1.45)	--	--
Sofosbuvir/ Velpatasvir ^c	400/100 once daily	24	1.44 (1.33 to 1.55)	1.40 (1.34 to 1.46)	1.84 (1.76 to 1.92)
Sofosbuvir/ Velpatasvir ^c	400/100 once daily	30	1.46 (1.39 to 1.54)	1.40 (1.44)	1.84 (1.61 to 1.79)
Sofosbuvir/ Velpatasvir/ Voxilaprevir ^c	400/100/100 once daily	29	1.36 (1.61)	1.34 (1.45)	1.38 (1.56)
Tacrolimus	0.05 mg/kg twice daily x 7 days	21	1.13 (1.10 to 1.27)	--	--
Tipranavir/ Ritonavir ^d	500/100 twice daily	22	1.32 (1.13)	1.2 (1.9 to 1.5)	1.2 (1.2 to 1.17)
	750/200 twice daily (23 doses)	20	1.38 (1.46 to 1.29)	1.2 (1.6 to 1.10)	1.14 (1.1 to 1.27)

Table 12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

12.2 Pharmacokinetics

12.3 Emtricitabine and Tenofovir Disoproxil Fumarate Tablets

12.4 Resistance

12.5 Pharmacokinetics

12.6 Resistance

12.7 Resistance

12.8 Resistance

12.9 Resistance

12.10 Resistance

12.11 Resistance

12.12 Resistance

12.13 Resistance

12.14 Resistance

12.15 Resistance

12.16 Resistance

12.17 Resistance

12.18 Resistance

12.19 Resistance

12.20 Resistance

12.21 Resistance

12.22 Resistance

12.23 Resistance

12.24 Resistance

12.25 Resistance

12.26 Resistance

12.27 Resistance

12.28 Resistance

12.29 Resistance

12.30 Resistance

12.31 Resistance

12.32 Resistance

12.33 Resistance

12.34 Resistance

12.35 Resistance

12.36 Resistance

12.37 Resistance

12.38 Resistance

12.39 Resistance

12.40 Resistance

12.41 Resistance

12.42 Resistance

12.43 Resistance

12.44 Resistance

12.45 Resistance

12.46 Resistance

12.47 Resistance

Table 11 Drug Interactions: Changes in Pharmacokinetic Parameters for Tenofovir in the Presence of the Coadministered Drug

Coadministered Drug	Dose of Coadministered Drug (mg)	N	% Change of Tenofovir Pharmacokinetic Parameters ^b (90% CI)		
			C _{max}	AUC	t _{1/2}
Atazanavir ^c	400 once daily x 14 days	33	1.14 (1.8 to 2.0)	1.24 (1.21 to 1.28)	1.22 (1.15 to 1.30)
Atazanavir/ Ritonavir ^c	300/100 once daily	12	1.34 (1.20 to 1.51)	1.30 (1.45)	1.36 (1.21 to 1.36)
Darunavir/ Ritonavir ^d	300/100 twice daily	12	1.24 (1.8 to 1.42)	1.22 (1.10 to 1.35)	1.37 (1.19 to 1.57)
Indinavir	800 three times daily x 7 days	13	1.14 (1.31 to 1.33)	--	--
Ledipasvir/ Sofosbuvir ^{e,1}	90/400 once daily x 10 days	24	1.47 (1.37 to 1.58)	1.35 (1.29 to 1.42)	1.47 (1.38 to 1.57)
Ledipasvir/ Sofosbuvir ^{e,2}	90/400 once daily x 14 days	23	1.54 (1.47 to 1.64)	1.59 (1.42 to 1.59)	1.59 (1.49 to 1.70)
Ledipasvir/ Sofosbuvir ^{e,3}	90/400 once daily x 14 days	15	1.73 (1.56 to 1.04)	1.78 (1.78 to 1.23)	1.63 (1.32 to 1.97)
Ledipasvir/ Sofosbuvir ^e	90/400 once daily x 14 days	14	1.32 (1.25 to 1.39)	1.31 (1.50)	1.91 (1.74 to 1.110)
Ledipasvir/ Sofosbuvir ^e	90/400 once daily x 10 days	29	1.61 (1.51 to 1.72)	1.65 (1.59 to 1.71)	1.15 (1.05 to 1.28)
Lopinavir/ Ritonavir	400/100 twice daily x 14 days	24	1.17 (1.12 to 1.25)	1.32 (1.38)	1.51 (1.37 to 1.66)
Saquinavir/ Ritonavir	1000/100 twice daily x 14 days	35	--	--	1.23 (1.16 to 1.30)
Sofosbuvir ^c	400 single dose	16	1.25 (1.8 to 1.45)	--	--
Sofosbuvir/ Velpatasvir ^c	400/100 once daily	24	1.44 (1.33 to 1.55)	1.40 (1.34 to 1.46)	1.84 (1.76 to 1.92)
Sofosbuvir/ Velpatasvir ^c	400/100 once daily	30	1.46 (1.39 to 1.54)	1.40 (1.44)	1.84 (1.61 to 1.79)
Sofosbuvir/ Velpatasvir/ Voxilaprevir ^c	400/100/100 once daily	29	1.36 (1.61)	1.34 (1.45)	1.38 (1.56)
Tacrolimus	0.05 mg/kg twice daily x 7 days	21	1.13 (1.10 to 1.27)	--	--
Tipranavir/ Ritonavir ^d	500/100 twice daily	22	1.32 (1.13)	1.2 (1.9 to 1.5)	1.2 (1.2 to 1.17)
	750/200 twice daily (23 doses)	20	1.38 (1.46 to 1.29)	1.2 (1.6 to 1.10)	1.14 (1.1 to 1.27)

a. Subjects received VIREAD 300 mg once daily.

b. Increase = +1; Decrease = -1; No Effect = --.

c. Reyataz Prescribing Information.

d. Prezista Prescribing Information.

e. Emtricitabine and Tenofovir Disoproxil Fumarate Tablets.

f. Comparison based on exposures when administered as atazanavir/ritonavir + FTC/DF.

g. Comparison based on exposures when administered as darunavir/ritonavir + FTC/DF.

h. Study conducted with ATRIPLA (efavirenz/FTC/DF) coadministered with HARVONI.

i. Study conducted with COMPLERA (FTC/rilpivirine/DF) coadministered with HARVONI.

j. Study conducted with emtricitabine and tenofovir disoproxil fumarate tablets (FTC/TDF) + dolutegravir coadministered with HARVONI.

k. Study conducted with ATRIPLA coadministered with SOVALD[®] (sofosbuvir).

l. Study conducted with COMPLERA coadministered with EPCLUSA, coadministration with EPLUSA also results in comparable increases in tenofovir exposures when TDF is administered as ATRIPLA, STRIBILD, emtricitabine and tenofovir disoproxil fumarate tablets + atazanavir/ritonavir, or emtricitabine and tenofovir disoproxil fumarate tablets + darunavir/ritonavir.

m. Administered as atazanavir + FTC/DF.

n. Comparison based on exposures when administered as darunavir + ritonavir + FTC/DF.

o. Study conducted with additional voxilaprevir 100 mg to achieve voxilaprevir exposures expected in HCV-infected patients coadministered with HARVONI.

p. Aipluvix Prescribing Information.

q. No effect on the pharmacokinetic parameters of the following coadministered drugs was observed with emtricitabine and tenofovir disoproxil fumarate tablets: abacavir, didanosine (buffered tablets), FTC, entecavir, and lamivudine.

r. Administered as atazanavir/ritonavir + FTC/DF.

s. Study conducted with additional voxilaprevir 100 mg to achieve voxilaprevir exposures expected in HCV-infected patients coadministered with HARVONI.

t. Aipluvix Prescribing Information.

u. Administered as atazanavir/ritonavir + FTC/DF.

v. Administered as atazanavir/ritonavir + FTC/DF.

w. Administered as atazanavir/ritonavir + FTC/DF.

x. Administered as atazanavir/ritonavir + FTC/DF.

y. Administered as atazanavir/ritonavir + FTC/DF.

z. Administered as atazanavir/ritonavir + FTC/DF.

aa. Administered as atazanavir/ritonavir + FTC/DF.

ab. Administered as atazanavir/ritonavir + FTC/DF.

ac. Administered as atazanavir/ritonavir + FTC/DF.

ad. Administered as atazanavir/ritonavir + FTC/DF.

ae. Administered as atazanavir/ritonavir + FTC/DF.

af. Administered as atazanavir/ritonavir + FTC/DF.

ag. Administered as atazanavir/ritonavir + FTC/DF.

ah. Administered as atazanavir/ritonavir + FTC/DF.

ai. Administered as atazanavir/ritonavir + FTC/DF.

aj. Administered as atazanavir/ritonavir + FTC/DF.

ak. Administered as atazanavir/ritonavir + FTC/DF.

al. Administered as atazanavir/ritonavir + FTC/DF.

am. Administered as atazanavir/ritonavir + FTC/DF.

an. Administered as atazanavir/ritonavir + FTC/DF.

ao. Administered as atazanavir/ritonavir + FTC/DF.

ap. Administered as atazanavir/ritonavir + FTC/DF.

aq. Administered as atazanavir/ritonavir + FTC/DF.

ar. Administered as atazanavir/ritonavir + FTC/DF.

as. Administered as atazanavir/ritonavir + FTC/DF.

at. Administered as atazanavir/ritonavir + FTC/DF.