

TENOF-EM Tablet

Emtricitabine and Tenofovir Disoproxil Fumarate (200mg/300mg)

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What TENOF-EM (Emtricitabine and Tenofovir DF) is used for

TENOF-EM is indicated in combination with other antiretroviral agents for the treatment of HIV-1 in adults.

TENOF-EM is indicated in combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in adults.

How TENOF-EM (Emtricitabine and Tenofovir DF) works

TENOF-EM contains two active substances, emtricitabine and tenofovir disoproxil. Both of these active substances are antiretroviral medicines which are used to treat HIV infection. Emtricitabine is a nucleoside reverse transcriptase inhibitor and tenofovir is a nucleotide reverse transcriptase inhibitor. However, both are generally known as NRTIs and they work by interfering with the normal working of an enzyme (reverse transcriptase) that is essential for the virus to reproduce itself.

Before you use TENOF-EM (Emtricitabine and Tenofovir DF)

- When you must not use it
Pregnancy and lactation

Do not take **TENOF-EM (Emtricitabine and Tenofovir DF)** if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take **TENOF-EM (Emtricitabine and Tenofovir DF)** if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it
Tell your doctor if you
 - have liver problems including hepatitis B virus infection
 - have kidney problems or receive kidney dialysis treatment
 - have bone problems
- Taking other medicines
Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.
 - other medicines that contain tenofovir or emtricitabine
 - medicines that contain lamivudine
 - adefovirEspecially tell your healthcare provider if you take:
 - didanosine
 - atazanavir
 - lopinavir with ritonavir

How to use TENOF-EM (Emtricitabine and Tenofovir DF)

- If you are taking TENOF-EM (Emtricitabine and Tenofovir DF) to reduce the risk of getting HIV, take TENOF-EM (Emtricitabine and Tenofovir DF) every day, not just when you think you have been at risk of HIV infection.
- If you are taking TENOF-EM (Emtricitabine and Tenofovir DF) to reduce the risk of getting HIV, do not stop taking TENOF-EM (Emtricitabine and Tenofovir DF) or miss any doses. Stopping use of TENOF-EM (Emtricitabine and Tenofovir DF), or missing doses, may increase your risk of getting HIV infection. Do not stop taking TENOF-EM (Emtricitabine and Tenofovir DF) without contacting your doctor.

- How much to use

The recommended dose is:
Adults: one tablet each day with or without food.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it
Use as directed by your doctor or pharmacist.
 - How long to use it
Continue taking **TENOF-EM (Emtricitabine and Tenofovir DF)** for as long as your doctor recommends.
 - If you forget to use it
Consult your doctor or pharmacist on what you should do if you forget to use it.
Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.
 - If you use too much (overdose)
Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.
- ## While you are using it
- Things you must do
Take your medicine exactly as your doctor has told you.
Tell all the doctors, dentists and pharmacists treating you that you are taking **TENOF-EM (Emtricitabine and Tenofovir DF)**.
Tell your doctor immediately if you become pregnant while taking this medication.
 - Things you must not do
Do not stop taking the medicine unless advised by your doctor.
Do not take any new medicines without consulting your doctor.

Do not give **TENOF-EM (Emtricitabine and Tenofovir DF)** to anyone else, even if they have the same symptoms or condition as you.

- Do not share or re-use needles or other injection equipment.
- Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.
- Do not have any kind of sex without protection. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

- Things to be careful of
Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

TENOF-EM (Emtricitabine and Tenofovir DF) have the following effects:

The most common side effects of emtricitabine and tenofovir disoproxil fumarate tablets include:

- diarrhea
- nausea

Visit your doctor or pharmacist immediately if you experience any side effects listed or not listed here after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of *TENOF-EM (Emtricitabine and Tenofovir DF)*

- Storage

Keep out of the reach and sight of children.
Store below 30 °C and protect from moisture.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of

medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

- Blue, capsule shaped, film coated tablets debossed with 'H' on one side and '124' on other side.

- Ingredients

- Active ingredient(s)
Emtricitabine
Tenofovir Disoproxil Fumarate

- Inactive ingredients

Starch, Pregelatinized, Lactose Monohydrate, Cellulose, microcrystalline, Croscarmellose sodium, Magnesium Stearate and Opadry II blue 32K10849.

- MAL number(s):

MAL16015041AZ

Manufacturer

Hetero Labs Limited,
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Product Registration Holder

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