

Tenofovir 300

Tenofovir Disoproxil Fumarate 300mg Film Coated Tablet

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1. WHAT TENOFOVIR 300 IS USED FOR:

Tenofovir 300 is indicated in combination with other antiretroviral agents for the treatment of Human Immunodeficiency Virus (HIV) infection in adults and pediatric patients over 12 years of age. Tenofovir 300 is also indicated for the treatment of chronic hepatitis B in adults.

2. HOW TENOFOVIR 300 WORKS:

In vivo, tenofovir DF is hydrolysed to tenofovir, which is then phosphorylated by cellular kinases to the pharmacologically active metabolite tenofovir diphosphate. Tenofovir diphosphate inhibits the activity of HIV reverse transcriptase by competing with the nucleotide deoxyadenosine 5'- triphosphate for incorporation into viral DNA. Once incorporated into viral DNA, it terminates DNA elongation because of lack of a ribose ring.

3. BEFORE YOU USE TENOFOVIR 300:

- When you must not use it

Tell your doctor immediately and do not take Tenofovir 300 if you are allergic (hypersensitive) to tenofovir, or any of the other ingredients of Tenofovir 300.

- Before you start to use it

Do not give Tenofovir 300 to children and adolescents under 12 years of age.

Take special care with Tenofovir 300

- Patients with history of liver disease, including hepatitis.

Caution should be observed when nucleoside analogs are used in patients with known risk factors for liver disease.

- Patients co-infected with HIV and HBV.

If you are coinfecting with HIV-1 and HBV, your doctor will prescribe Tenofovir 300 as part of an appropriate antiretroviral combination regimen.

- Impaired Renal Function

Your doctor will recommend that the dosing interval for tenofovir DF be modified in patients with creatinine clearance <50 mL/min or in patients who require dialysis.

- Bone problem

Bone monitoring should be considered for HIV-infected patients who have a history of pathologic bone fracture or are at substantial risk for osteopenia

Pregnancy and breast-feeding

You must not take Tenofovir 300 during pregnancy unless specifically discussed with your doctor. There are no adequate and well-controlled studies in pregnant women. Tenofovir 300 should be used during pregnancy only if clearly needed.

Do not breast-feed during treatment with Tenofovir 300. It is not known whether tenofovir is excreted into human breast milk and the potential for adverse effects in the nursing infant from exposure to the drug are unknown.

- 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.

Inform your doctor if you are taking Other medicines containing didanosine (for HIV infection). Notable drug interactions occur when tenofovir DF is administered with didanosine or atazanavir.

4. HOW TO USE TENOFOVIR 300:

Take Tenofovir 300 without regard to food (for example, a meal or a snack).

- How much to use

Adults:

One tablet each day without regard to food

Not for children and adolescents (under 12 years of age).

Always take the dose recommended by your doctor. Do not change the dose unless your doctor tells you to.

Follow all directions given to you by your doctor and pharmacist carefully. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- How long to use it

Continue taking Tenofovir 300 for as long as your doctor recommends.

Don't stop taking Tenofovir 300 without your doctor's advice. Stopping treatment with Tenofovir 300 may reduce the effectiveness of the treatment recommended by your doctor. Talk to your doctor before you stop taking Tenofovir 300 for any reason, particularly if you are experiencing any side effects or you have another illness.

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- 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.

5. WHILE YOU ARE USING TENOHOPE 300

- 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 Tenofovir 300.

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 Tenofovir 300 to anyone else, even if they have the same symptoms or condition as you.

- 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.

6. SIDE EFFECTS

Like all medicines, Tenofovir 300 can cause side effects, although not everybody gets them.

Very common side effects

- Diarrhoea, being sick (vomiting), feeling sick (nausea), dizziness

Common side effects

- Headache, stomach pain, feeling tired, feeling bloated, flatulence

Rare side effects

- Excess lactic acid in the blood (lactic acidosis, a serious side effect that can be fatal). The following side effects may be signs of lactic acidosis:

- o Deep rapid breathing
 - o Drowsiness
 - o Feeling sick (nausea), being sick (vomiting) and stomach pain.
- If you think you may have lactic acidosis, contact your doctor immediately.

- Pain in the tummy (abdomen) caused by inflammation of the pancreas
- Changes to your urine and back pain caused by kidney problems, including renal failure
- Rash

Very rare side effects

- Shortness of breath
- Pain in the tummy (abdomen) caused by inflammation of the liver
- Feeling weak

Other possible effects

- You may also experience muscle pain or weakness, inflammation of

the kidney, passing a lot of urine and feeling thirsty.

- In the treatment of HIV, combination antiviral (including tenofovir) may change your body shape, by changing the way body fat is distributed. You may lose fat from your legs, arms and face; gain fat going around the tummy (abdomen) and internal organs; get larger breasts or fatty lumps on the back of the neck ('buffalo hump').

- The cause and the long-term effects of these changes are not yet known.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

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)]

7. STORAGE AND DISPOSAL OF TENOHOPE 300

Storage

Store in the original container. Protect from moisture. Store below 30°C

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.

8. PRODUCT DESCRIPTION

What it looks like and contents of the pack

Blue coloured, oval shaped, biconvex film coated tablets debossed 'CL 77' on one side and plain surface on other side.

Tenofope 300

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What Tenofope 300 contains

Active ingredient:

Tenofovir Disoproxil Fumarate

Excipients:

Lactose Monohydrate

Microcrystalline Cellulose

Pregelatinised Starch

Croscarmellose Sodium

Magnesium Stearate

Opadry II Blue 30K505001

Purified Water

MAL No:

MALXXXXXXXXX

9. MANUFACTURER AND PRODUCT REGISTRATION HOLDER

Manufacturer:

**Macleods Pharmaceuticals
Limited.**

Plot No. 25-27, Survey No .366,
Premier Industrial Estate, Kachigam,
Daman, Dadra, and Nagar Haveli and
Dam 396210, India

PRODUCT REGISTRATION HOLDER:

**Macleods Pharmaceuticals Sdn.
Bhd.**

A2-27-1 Soho Suites KLCC, Jalan
Perak, 50450 Kuala Lumpur,
Malaysia

10. DATE OF REVISION:

06/02/2026

11. SERIAL NUMBER

NPRA (R2) 25/094