

Tenolon 300mg Film Coated Tablet

Tenofovir Disoproxil Fumarate (300mg)

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What *Tenolon* is used for

Tenolon 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.

Tenolon is also indicated for the treatment of chronic hepatitis B in adults.

How *Tenolon* 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.

Before you use *Tenolon*

- When you must not use it

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

- Before you start to use it

Do not give *Tenolon* to children and adolescents under 12 years of age.

Take special care with *Tenolon*

- *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 *Tenolon* 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 *Tenolon* during pregnancy unless specifically discussed with your doctor. There are no adequate and well-controlled studies in pregnant women. *Tenolon* should be used during pregnancy only if clearly needed.

Do not breast-feed during treatment with *Tenolon*. 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.

How to use *Tenolon*

Take *Tenolon* with food (for example, a meal or a snack).

- How much to use

Adults: One tablet each day with 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 *Tenolon* for as long as your doctor recommends.

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

- 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 *Tenolon*.

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 *Tenolon* 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.

Side effects

Like all medicines, *Tenolon* 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:

- Deep rapid breathing
- Drowsiness
- 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)]

Storage and Disposal of *Tenolon*

- Storage

Preserve in tightly closed container, store not above 30°C at dry place

- 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

Tenolon are blue, almond-shaped, film coated tablets with white cores, debossed with "LZ30" on one side and with "300" on the other side.

- Ingredients

- Active ingredient

Each film coated tablet contains 300 mg of tenofovir disoproxil fumarate equivalent to tenofovir disoproxil 245mg.

- Inactive ingredients

Croscarmellose Sodium, Lactose Monohydrate, Microcrystalline Cellulose, Pregelatinized Starch, Purified Water, Magnesium Stearate and Opadry.

- Pack size: HDPE bottle of 30 Tablets

- MAL number

MAL23086009AZ

Manufacturer

Shijiazhuang Lonzeal Pharmaceuticals Co., Ltd
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Product Registration Holder

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