

FORSTAVIR

TENOFOVIR DISOPROXIL FUMARATE 300MG

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What FORSTAVIR is used for

FORSTAVIR is used for the treatment of Human Immunodeficiency Virus (HIV) infection in patients over 12 years of age. FORSTAVIR is also used to treat chronic hepatitis B, an infection with hepatitis B virus (HBV), in adults.

How FORSTAVIR works

Tenofovir is a nucleotide reverse transcriptase inhibitor, generally known as an NRTI and works by interfering with the normal working of enzymes (in HIV: reverse transcriptase; in hepatitis B: DNA polymerase) that are essential for the viruses to reproduce themselves.

Before you use FORSTAVIR

- When you must not use it

Do not take FORSTAVIR

If you are allergic (hypersensitive) to tenofovir, or any of the other ingredients of FORSTAVIR.

If this applies to you, tell your doctor immediately and don't take FORSTAVIR.

- Before you start use it

Take special care with FORSTAVIR

- **Tell your doctor if you have had kidney disease or if tests have shown problems with your kidneys.** FORSTAVIR may affect your kidneys. Before starting treatment, your doctor may order blood tests to check your kidney function and may advise you to take the tablets less often. Your doctor may also order blood tests during treatment to monitor your kidneys. FORSTAVIR are not usually taken with other medicines that can damage your kidneys (see taking other medicines). If this is unavoidable, your doctor will monitor your kidney function once a week.
- **Talk to your doctor if you are over 65.** FORSTAVIR has not been studied in patients over 65 years of age. If you are older than this and are

prescribed FORSTAVIR, your doctor will monitor you carefully

- Do not give FORSTAVIR to children and adolescents under 12 years of age.
- Talk to your doctor if you have a history of liver disease, including hepatitis. Patients with liver disease including chronic hepatitis B or C, who are treated with antiretrovirals, have a higher risk of severe and potentially fatal liver complications. If you have hepatitis B infection, your doctor will carefully consider the best treatment for you. If you have a history of liver disease or chronic hepatitis B infection your doctor may conduct blood tests to monitor your liver function.
- **Take care not to infect other people.** FORSTAVIR do not reduce the risk of passing on HIV or HBV to others through sexual contact or blood contamination. You must continue to take precautions to avoid this.

Other precautions

In the treatment of HIV, combination antiretroviral therapies (including FORSTAVIR) may raise blood sugar, increase blood fats (hyperlipaemia), cause changes to body fat, and resistance to insulin.

If you are diabetic, overweight or have high cholesterol, talk to your doctor.

Look out for infections. If you have advanced HIV infection (AIDS) and have an infection, you may develop symptoms of infection and inflammation or worsening of the symptoms of an existing infection once treatment with FORSTAVIR is started. These symptoms may indicate that your body's improved immune system is fighting infection.

Look out for signs of inflammation or infection soon after you start taking FORSTAVIR. If you notice signs of inflammation or infection, **tell your doctor at once.**

Bone problems. Some patients with HIV taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). The length of combination antiretroviral therapy, corticosteroid use, alcohol consumption, severe immunosuppression, higher body mass index, among others, may be some of the many risk factors for developing this disease. Signs of osteonecrosis are joint

stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms tell your doctor.

Bone problems (sometimes resulting in fractures) may also occur due to damage to kidney tubule cells.

Pregnancy and breast-feeding

Ask your doctor for advice before taking any medicine

- **You must not take FORSTAVIR during pregnancy unless** specifically discussed with your doctor.
- **Do not breast-feed during treatment with FORSTAVIR.**

Driving and using machines

FORSTAVIR can cause dizziness. If you feel dizzy while taking FORSTAVIR, do not drive and do not use any tools or machines.

Important information about some of the ingredients of FORSTAVIR

FORSTAVIR contains lactose. Tell your doctor before taking FORSTAVIR if you cannot tolerate lactose or if you have an intolerance to any other sugars.

- Taking other medicines

Do not take FORSTAVIR if you are already taking other medicines containing tenofovir disoproxil fumarate. Do not take FORSTAVIR and adefovir dipivoxil at the same time.

Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

It is very important to tell your doctor if you are taking other medicines that may damage your kidneys.

These include:

- aminoglycosides, pentamidine or vancomycin (for bacterial infection)
- amphotericin B (for fungal infection)
- foscarnet, ganciclovir, or
- cidofovir (for viral infection)
- interleukin-2 (to treat cancer)
- adefovir dipivoxil (for HBV)
- tacrolimus (for suppression of the immune system)
- **Other medicines containing didanosine (for HIV infection):** Taking FORSTAVIR with other antiviral medicines that contain didanosine can raise the levels of didanosine in your blood and may reduce CD4 cell counts. Rarely, inflammation of the pancreas and lactic acidosis (excess lactic acid in the blood), which sometimes caused

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death, have been reported when medicines containing tenofovir disoproxil fumarate and didanosine were taken together. Your doctor will carefully consider whether to treat you with combinations of tenofovir and didanosine.

- **Don't stop any anti-HIV medicines** prescribed by your doctor when you start FORSTAVIR if you have both HBV and HIV.

Taking FORSTAVIR with food and drink

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

How to use FORSTAVIR

- How much to use

Adults: one tablet each day with food (for example, a meal or a snack).

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

- **Always take the dose recommended by your doctor.** This is to make sure that your medicine is fully effective, and to reduce the risk of developing resistance to the treatment. Do not change the dose unless your doctor tells you to.
- **If you have problems with your kidneys,** your doctor may advise you to take FORSTAVIR less frequently.
- **Don't stop any anti-HIV medicines** prescribed by your doctor when you start FORSTAVIR if you have both HBV and HIV.

If you have HBV your doctor may offer you an HIV test to see if you have both HBV and HIV.

Please refer to the patient information leaflets of the other antiretrovirals for guidance on how to take those medicines.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking FORSTAVIR for as long as your doctor recommends.

If you stop taking FORSTAVIR

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

If you have hepatitis B or HIV and hepatitis B together (co-infection), it is very important not to stop your FORSTAVIR treatment without talking to your doctor first. Some patients have had blood tests or symptoms indicating that their hepatitis has got worse after stopping FORSTAVIR. You may require blood tests for several months after stopping treatment.

Tell your doctor immediately about new or unusual symptoms after you stop treatment, particularly symptoms you associate with hepatitis B infection.

- 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 FORSTAVIR.

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

- Things to be careful of

This medicine is not a cure for HIV infection. While taking FORSTAVIR you may still develop infections or other illnesses associated with HIV infection. You can also pass on HIV or HBV to others, so it is important to take precautions to avoid infecting other people.

Side effects

Very common side effects include the following:

- hypophosphatemia (low level of

phosphate in the blood)

- dizziness
- diarrhea, vomiting, nausea
- rash
- asthenia (lack of energy)

Common side effects include the following:

- abdominal pain, abdominal distension, flatulence
- headache
- increased transaminases (Liver enzyme)
- bone mineral density decreased
- fatigue

Uncommon side effects include the following:

- hypokalaemia
- pancreatitis
- rhabdomyolysis, muscular weakness
- increase creatinine, proximal renal tubulopathy (including Fanconi syndrome)

Rare side effects include the following:

- lactic acidosis
- hepatic steatosis, hepatitis
- Angioedema
- osteomalacia (manifested as bone pain and infrequently contributing to fractures), myopathy
- acute renal failure, renal failure, acute tubular necrosis, nephritis (including acute interstitial nephritis), nephrogenic diabetes insipidus.

Combination antiretroviral therapy has been associated with metabolic abnormalities such as hypertriglyceridemia, hypercholesterolemia, insulin resistance, hyperglycemia and hyperlactatemia.

Combination antiretroviral therapy has been associated with redistribution of body fat (lipodystrophy) in HIV patients including the loss of peripheral and facial subcutaneous fat, increased intra-abdominal and visceral fat, breast hypertrophy and dorsocervical fat.

The following adverse reactions, listed under the body system headings above, may occur as a consequence of proximal renal tubulopathy: rhabdomyolysis, osteomalacia (manifested as bone pain and infrequently contributing to fractures), hypokalemia, muscular weakness, myopathy and hypophosphatemia.

These events are not considered to be causally associated with tenofovir disoproxil fumarate therapy in the absence of proximal renal tubulopathy.

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

Serial number

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

Storage and Disposal of FORSTAVIR**- Storage**

Keep out of the reach and sight of children.

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.

Product Description**- What it looks like**

FORSTAVIR are off-white, oval shaped, biconvex, film coated tablets debossed with 'I' on one side and '36' on the other side.

- Ingredients**- Active ingredients**

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 II White.

- MAL number:

MAL18016034AZ

Manufacturer

Aurobindo Pharma Limited (Unit III),
Survey No. 313 & 314,
Bachupally Village, Bachupally
Mandal, Medchal-Malkajgiri District,
Telangana State, INDIA.

Product Registration Holder Unimed Sdn Bhd

No 53, Jalan Tembaga SD 5/2B, Bandar
Sri Damansara,
52200 Kuala Lumpur.

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