

MyTAFf 25mg (TENOFVIR ALAFENAMIDE TABLETS)

Tenofovir alafenamide 25 mg

What is in this leaflet

1. What MYTAFf is used for
2. How MYTAFf works
3. Before you take MYTAFf
4. How to take MYTAFf
5. While you are taking MYTAFf
6. Side effects
7. Storage and disposal of MYTAFf
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision

1. What MYTAFf is used for
MYTAFf is used to **treat chronic (long term) hepatitis B** in adults and adolescents aged 12 years and older, who weigh at least 35 kg. Hepatitis B is an infection affecting the liver, caused by the hepatitis B virus.

2. How MYTAFf works
MYTAFf contains the active substance *tenofovir alafenamide*. This is an *antiviral medicine*, known as a *nucleotide reverse transcriptase inhibitor* (NtRTI). In patients with hepatitis B, MYTAFf controls the infection by stopping the virus from multiplying.

3. Before you take MYTAFf

When you must not use it:

Do not take MYTAFf

• **if you are allergic** to tenofovir alafenamide or any of the other ingredients of this medicine (listed in section 8).
If this applies to you, **do not take MYTAFf and tell your doctor immediately**.

Before you start to use it:

• **Take care not to pass on your hepatitis B to other people.**

You can still infect others when taking this medicine. MYTAFf does not reduce the risk of passing on hepatitis B to others through sexual contact or blood contamination. You must continue to take precautions to avoid this. Discuss with your

doctor the precautions needed to avoid infecting others.

• **Tell your doctor if you have a history of liver disease.** Patients with liver disease, who are treated for hepatitis B with antiviral medicines, have a higher risk of severe and potentially fatal liver complications. Your doctor may need to carry out blood tests to monitor your liver function.

• **Talk to your doctor or pharmacist if you have had kidney disease or if tests have shown problems with your kidneys.** Before starting treatment and during treatment, your doctor may order blood tests to monitor how your kidneys work.

• **Talk to your doctor if you also have hepatitis C or D.** MYTAFf has not been tested on patients who have hepatitis C or D as well as hepatitis B.

• **Talk to your doctor if you also have HIV.** If you are not sure whether you have HIV, your doctor should offer you HIV testing before you start taking MYTAFf for hepatitis B.

If any of these apply to you, **talk to your doctor before taking MYTAFf**.

Children and adolescents: Do not give this medicine to children who are under 12 years old or weigh less than 35 kg. MYTAFf has not been tested in children aged less than 12 years old or weighing less than 35 kg.

Taking other medicines:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

MYTAFf may interact with other medicines. As a result, the

amounts of MYTAFf or other medicines in your blood may change. This may stop your medicines from working properly, or may make any side effects worse.

Medicines used in treating hepatitis B infection

Do not take MYTAFf with other medicines containing:

- **tenofovir alafenamide**
- **tenofovir disoproxil fumarate**
- **adefovir dipivoxil**

Other types of medicines Talk to your doctor if you are taking:

- **antibiotics** used to treat bacterial infections including tuberculosis, containing:
 - rifabutin, rifampicin or rifapentine
- **antiviral medicines used to treat HIV**, such as:
 - ritonavir or cobicistat boosted darunavir, lopinavir or atazanavir
- **anticonvulsants** used to treat epilepsy, such as:
 - carbamazepine, oxcarbazepine, phenobarbital or phenytoin
- **herbal remedies** used to treat depression and anxiety, containing:
 - St. John's wort (*Hypericum perforatum*)
- **antifungal medicines** used to treat fungal infections, containing:
 - ketoconazole or itraconazole

Tell your doctor if you are taking these or any other medicines

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

• **Take steps to avoid getting pregnant** during treatment with MYTAFf. You must use an effective method of contraception. Tell your doctor immediately if you become pregnant.

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• **Do not breast-feed during treatment with MYTAFf.** It is recommended that you do not breast-feed to avoid passing tenofovir alafenamide or tenofovir to the baby through breast milk.

MYTAFf contains lactose
Tell your doctor if you are lactose-intolerant or intolerant to other sugars

4. How to take MYTAFf
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much and how long to use it:

The recommended dose is **one tablet once a day with food**. Treatment should continue for as long as your doctor tells you. Usually this is for at least 6 to 12 months and may be for many years.

If you forget to take MYTAFf It is important not to miss a dose of MYTAFf. If you do miss a dose, work out how long since you should have taken it.

• **If it is less than 18 hours** after you usually take MYTAFf, take it as soon as you can, and then take your next dose at its regular time.

• **If it is more than 18 hours** after you usually take MYTAFf, then do not take the missed dose. Wait and take the next dose at the regular time. **Do not take a double dose** to make up for a forgotten tablet.

If you are sick (vomit) less than 1 hour after taking MYTAFf, take another tablet. You do not need to take another tablet if you are sick (vomit) more than 1 hour after taking MYTAFf.

If you take more MYTAFf than you should (overdose)

If you accidentally take more than the recommended dose of MYTAFf you may be at increased risk of experiencing possible side effects with this medicine (see section 6, for *side effects*).

Contact your doctor or nearest emergency department immediately for advice. Keep the tablet bottle with you so that you can easily describe what you have taken.

5. While you are taking MYTAFf

Things you must do:

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure

Things you must not do:

Do not stop taking MYTAFf without your doctor's advice. Stopping treatment with MYTAFf may cause your hepatitis B to get worse. In some patients with advanced liver disease or cirrhosis, this could be life-threatening. If you stop taking MYTAFf, you will need regular health checks and blood tests for several months to check your hepatitis B infection.

• **Talk to your doctor** before you stop taking MYTAFf for any reason, particularly if you are experiencing any side effects or you have another illness.

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

• **Talk to your doctor** before you restart taking MYTAFf tablets.

If you have any further questions

on the use of this medicine, ask your doctor or pharmacist.

Things to be careful of: **Driving and using machines** MYTAFf can cause dizziness. If you feel dizzy when taking MYTAFf, do not drive and do not use any tools or machines.

6. Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common side effects

- Headache

Common side effects

- Diarrhoea
- Being sick (*vomiting*)
- Feeling sick (*nausea*)
- Dizziness
- Stomach pain
- Joint pain (*arthralgia*)
- Rash
- Itchiness
- Feeling bloated
- Wind (*flatulence*)
- Feeling tired

Tests may also show:

- Increased level of a liver enzyme (ALT) in the blood

If any of these side effects get serious tell your doctor.

Reporting of side effects If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. 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)]. By reporting side effects you can help provide more information on the safety of this medicine.

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7. Storage and disposal of MYTAFf

Storage

Store in a dry place below 30°C
Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the bottle and carton after {EXP}. The expiry date refers to the last day of that month.
Store in the original package in order to protect from moisture. Keep the bottle tightly closed.

Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

8. Product Description

What MYTAFf looks like and contents of the pack:

A white to off-white, film-coated, round, biconvex tablet debossed with M on one side of the tablet and TFI on other side.

The following pack size is available: outer cartons containing 1 HDPE bottle of 30 film-coated tablets (with a silica gel desiccant that must be kept in the bottle to help protect your tablets). The silica gel desiccant is contained in a separate sachet or canister and should not be swallowed.

What MYTAFf contains:

The active substance is *tenofovir alafenamide*. Each MYTAFf film-coated tablet contains tenofovir alafenamide fumarate, equivalent to 25 mg of tenofovir alafenamide.

The other ingredients are

Tablet core:

Lactose monohydrate,
microcrystalline cellulose,
croscarmellose sodium,
magnesium stearate.

Film-coating:

Polyvinyl alcohol, titanium dioxide, macrogol, talc

MAL No: 20076048AZ

9. Manufacturer and Product Registration Holder *Manufacturer*
Mylan Laboratories Limited Plot no: 11-12 & 13, Indore SEZ, Pharma Zone, Phase-II, Sector-III, Pithampur – 454775
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Product Registration Holder

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10. Date of revision

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