

Patient Information leaflet

SCHEDULING STATUS

S4

IVATEBI 200 mg/25 mg film-coated tablets emtricitabine/tenofovir alafenamide

Sugar free

WARNING:

TOO MUCH LACTIC ACID IN YOUR BLOOD (LACTIC ACIDOSIS) IS A SERIOUS BUT RARE MEDICAL EMERGENCY THAT CAN LEAD TO DEATH. TELL YOUR HEALTHCARE PROVIDER RIGHT AWAY IF YOU GET THESE SYMPTOMS:

WEAKNESS OR BEING TIRED MORE THAN USUAL, UNUSUAL MUSCLE PAIN, BEING

SHORT OF BREATH OR FAST BREATHING, STOMACH PAIN WITH NAUSEA AND VOMITING, COLD OR BLUE HANDS AND FEET, FEEL DIZZY OR LIGHTEADED, OR A FAST OR ABNORMAL HEARTBEAT.

IF YOU HAVE HEPATITIS B INFECTION, YOUR DOCTOR WILL CAREFULLY CONSIDER THE BEST TREATMENT REGIMEN FOR YOU. IF YOU HAVE HEPATITIS B INFECTION, LIVER PROBLEMS MAY BECOME WORSE AFTER YOU STOP TAKING IVATEBI. IT IS IMPORTANT NOT TO STOP TAKING IVATEBI WITHOUT TALKING TO YOUR DOCTOR. YOU MUST REMAIN UNDER THE CARE OF YOUR DOCTOR WHILE TAKING IVATEBI.

Read all of this leaflet carefully before you start taking IVATEBI because it contains important information for you.

Signature:



- Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your ask your doctor, pharmacist, nurse or healthcare provider.

- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours

What is in this leaflet

1. What IVATEBI is and what it is used for
2. What you need to know before you take IVATEBI
3. How to take IVATEBI
4. Possible side effects
5. How to store IVATEBI
6. Contents of the pack and other information

1. What IVATEBI is and what it is used for

IVATEBI contains two active substances:

- emtricitabine, an antiretroviral medicine of a type known as a nucleoside reverse transcriptase inhibitor (NRTI)
- tenofovir alafenamide, an antiretroviral medicine of a type known as a nucleotide reverse transcriptase inhibitor (NtRTI)

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IVATEBI blocks the action of the reverse transcriptase enzyme, which is essential for the virus to multiply. IVATEBI therefore reduces the amount of HIV in your body.

IVATEBI in combination with other medicines is for the treatment of human immunodeficiency virus 1 (HIV-1) infection in adults and adolescents 12 years of age and older, who weigh at least 35 kg.

2. What you need to know before you take IVATEBI Do not take IVATEBI:

If you are allergic to emtricitabine, tenofovir alafenamide or any of the other ingredients of this medicine (listed in section 6 of this leaflet).

Warnings and precautions

Too much lactic acid in your blood (lactic acidosis) is a serious but rare medical emergency that can lead to death. Tell your healthcare provider right away if you get these symptoms: weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, stomach pain with nausea and vomiting, cold or blue hands and feet, feel dizzy or lightheaded, or a fast or abnormal heartbeat.

If you have hepatitis B infection, your doctor will carefully consider the best treatment regimen for you. If you have hepatitis B infection, liver problems may become worse after you stop taking IVATEBI. It is important not to stop taking IVATEBI without talking to your doctor.

You must remain under the care of your doctor while taking IVATEBI.

You can still pass on HIV when taking IVATEBI. Discuss with your doctor the precautions needed to avoid infecting other people. IVATEBI is not a cure for HIV infection. While taking IVATEBI you may still develop infections or other illnesses associated with HIV infection.

During HIV therapy such as with IVATEBI there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and lifestyle, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

Autoimmune disorders (the immune system attacks healthy body tissue), may also occur after you start taking medicines for HIV infection such as IVATEBI. Autoimmune disorders may occur many months after the start of treatment. Look out for any symptoms of infection or other symptoms such as:

- muscle weakness
- weakness beginning in the hands and feet and moving up towards the trunk of the body
- palpitations, tremor or hyperactivity

Talk to your doctor before taking IVATEBI:

If you have liver problems or have suffered 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 regimen for you.

Signature:



- If you have hepatitis B liver problems it may become worse after you stop taking IVATEBI.

Do not stop taking IVATEBI without talking to your doctor: see section 3, Do not stop taking IVATEBI.

- Your doctor may not prescribe IVATEBI to you if the virus has a K65R mutation.

While you are taking IVATEBI

Once you start taking IVATEBI, look out for:

- Signs of inflammation or infection
- Any signs of inflammation or infection. In some patients with advanced HIV infection (AIDS) and who have had opportunistic infections in the past (infections that occur in people with a weak immune system), signs and symptoms of inflammation from previous infections may occur soon after antiretroviral treatment, such as with IVATEBI, is started. It is thought that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms.
- Joint pain, stiffness or bone problems
- Bone problems. Some patients taking combination antiretroviral medicines such as IVATEBI may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). Taking this type of medicine for a long time, taking corticosteroids, drinking alcohol, having a very weak immune system, and being overweight, may be some of the many risk factors for developing this disease. Signs of osteonecrosis are:
 - joint stiffness

- joint aches and pains (especially of the hip, knee and shoulder)
- difficulty with movement

If you notice any of these symptoms, tell your doctor immediately. For more information see section 4, Possible side effects.

Although kidney problems have not been observed with IVATEBI, there is a possibility that you may experience kidney problems when taking IVATEBI over a long period of time.

Children and adolescents

Do not give this medicine to children under 12 years of age or weighing less than 35 kg. The use of IVATEBI in children under 12 years of age has not been studied.

Other medicines and IVATEBI

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. IVATEBI may interact with other medicines. As a result, the amounts of IVATEBI or other medicines in your blood may change. This may stop your medicines from working properly or may make any side effects worse. In some cases, your doctor may need to adjust your dose or check your blood levels.

- Medicines used in treating hepatitis B infection:

You should not take IVATEBI with medicines containing:

- tenofovir alafenamide
- tenofovir disoproxil

Signature:



- lamivudine
- adefovir dipivoxil

Tell your doctor if you are taking any of these medicines.

Other types of medicine:

Talk to your doctor if you are taking:

antibiotics, used to treat bacterial infections including tuberculosis, containing:

- rifabutin, rifampicin, and rifapentine

antiviral medicines used to treat HIV:

- emtricitabine and tipranavir

anticonvulsants, used to treat epilepsy, such as:

- carbamazepine, oxcarbazepine, phenobarbitone and phenytoin

herbal remedies used to treat depression and anxiety containing:

- St. John's wort (*Hypericum perforatum*)

Tell your doctor if you are taking these or any other medicines. Do not stop your treatment without contacting your doctor.

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 IVATEBI.

Signature:



Use effective contraception while taking IVATEBI.

Ask your doctor or pharmacist for advice before taking any medicine when pregnant.

If you have taken IVATEBI during your pregnancy, your doctor may request regular blood tests and other diagnostic tests to monitor the development of your child. In children whose mothers took NRTIs during pregnancy, the benefit from the protection against HIV outweighed the risk of side effects.

Do not breast-feed your baby during treatment with IVATEBI.

One of the active substances in IVATEBI (emtricitabine) passes into breast milk and possible harm to your baby cannot be excluded.

It is also recommended that you do not breast-feed your baby to avoid passing the HIV virus to the baby through your breast milk.

Driving and using machines

IVATEBI may affect your ability to drive and use machines. Do not drive and use machines until you know how treatment with IVATEBI affects you.

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IVATEBI can cause dizziness and fatigue/tiredness. If you feel tired and/or dizzy when taking

IVATEBI, do not drive and do not use any tools or machines.

3. How to take IVATEBI

Do not share medicines prescribed for you with any other person.

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

The recommended dose is:

Adults: one tablet each day, with or without food

Adolescents 12 years of age and older, who weigh at least 35 kg: one tablet each day with or without food.

Do not chew, crush or split the tablet.

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 are on dialysis, take your daily dose of IVATEBI following completion of dialysis.

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If you take more IVATEBI than you should:

If you take more than the recommended dose of IVATEBI you may be at higher risk of side effects of IVATEBI (see section 4, Possible side effects).

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

If you forget to take IVATEBI

It is important not to miss a dose of IVATEBI. If you do miss a dose:

If you notice within 18 hours of the time you usually take IVATEBI, you must take the tablet as soon as possible. Then take the next dose as usual.

If you notice 18 hours or more after the time you usually take IVATEBI, then do not take the missed dose. Wait and take the next dose at your usual time.

If you vomit less than 1 hour after taking IVATEBI, take another tablet.

Do not stop taking IVATEBI

Do not stop taking IVATEBI without talking to your doctor. Stopping IVATEBI can seriously affect how well future treatment works. If IVATEBI is stopped for any reason, speak to your doctor before you restart taking IVATEBI tablets.

Signature:



When your supply of IVATEBI starts to run low, get more from your doctor or pharmacist. This is

very important because the amount of virus may start to increase if IVATEBI is stopped for even a short time. The disease may then become harder to treat.

If you have both HIV infection and hepatitis B, it is very important not to stop taking IVATEBI without talking to your doctor first. You may require blood tests for several months after stopping treatment. In some patients with advanced liver disease or cirrhosis, stopping treatment may lead to worsening of hepatitis, which may be life-threatening.

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

If you have any further questions on the use of IVATEBI, ask your doctor or pharmacist.

4. Possible side effects

IVATEBI can have side effects.

Not all side effects reported for IVATEBI are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking IVATEBI, please consult your healthcare provider for advice.

If any of the following happens, stop taking IVATEBI and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing

Signature:



- Rash or itching
- Fainting.

These are all very serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- Abnormal dreams
- Headache
- Dizziness
- Nausea
- Diarrhoea
- Vomiting
- Abdominal pain
- Flatulence (passing of wind (air or gas) from the intestine and through the anus)
- Fatigue.

Less frequent side effects

- Anaemia (decreased red blood cell count)
- Dyspepsia (indigestion or heartburn)
- Arthralgia (joint pain).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. How to store IVATEBI

Store all medicines out of reach of children.

Signature:



Do not use this medicine after the expiry date, which is stated on the carton, label, bottle. 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. Store at or below 30 °C.

Return all unused medicine to your pharmacist Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What IVATEBI contains

The active substances are emtricitabine and tenofovir alafenamide. Each IVATEBI film-coated tablet contains either:

200 mg of emtricitabine and tenofovir alafenamide fumarate equivalent to 25 mg of tenofovir alafenamide

IVATEBI also contains the following other ingredients:

Microcrystalline cellulose, croscarmellose sodium, magnesium stearate, Polyvinyl alcohol, titanium dioxide, macrogol 3350, talc, indigo carmine aluminium lake (E132).

What IVATEBI looks like and contents of the pack

IVATEBI blue, film-coated, rectangular, biconvex, bevelled edge tablet debossed with M on one side of the tablet and EA I on the other side.

IVATEBI comes in bottles of 30 tablets (with a silica gel desiccant that must be kept in the bottle to help protect your tablets).

Signature:



Applicant (HCR): Viatris Healthcare (Pty) Ltd

Application name (number): IVATEBI - 561088 (master)

The following pack sizes are available: 1 bottle of 30 film-coated tablets.

Date: 24/10/2023

Holder of Certificate of Registration

Viatris Healthcare (Pty) Ltd,

4 Brewery Street

Isando

Johannesburg

1600

This leaflet was last revised in

N/A

Registration Number

To Be Allocated

Signature:

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