Patient Information leaflet

SCHEDULING STATUS

S4

ATEBIVA 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 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.

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

- 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 ATEBIVA is and what it is used for

ATEBIVA 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)

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

ATEBIVA 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 ATEBIVA Do not take ATEBIVA:

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 ATEBIVA. It is important not to stop taking ATEBIVA without talking to your doctor.

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

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

During HIV therapy such as with ATEBIVA 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 ATEBIVA. 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 ATEBIVA:

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.

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

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

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

While you are taking ATEBIVA

Once you start taking ATEBIVA, 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 ATEBIVA, 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 ATEBIVA 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 ATEBIVA, there is a possibility that you may experience kidney problems when taking ATEBIVA 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 ATEBIVA in children under 12 years of age has not been studied.

Other medicines and ATEBIVA

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. ATEBIVA may interact with other medicines. As a result, the amounts of ATEBIVA 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 ATEBIVA with medicines containing:

- tenofovir alafenamide
- tenofovir disoproxil

- 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 ATEBIVA.

Use effective contraception while taking ATEBIVA.

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

If you have taken ATEBIVA 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 ATEBIVA.

One of the active substances in ATEBIVA (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

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

ATEBIVA can cause dizziness and fatigue/tiredness. If you feel tired and/or dizzy when taking ATEBIVA, do not drive and do not use any tools or machines.

3. How to take ATEBIVA

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

Always take ATEBIVA 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 ATEBIVA following completion of dialysis.

If you take more ATEBIVA than you should:

If you take more than the recommended dose of ATEBIVA you may be at higher risk of side effects of ATEBIVA (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 ATEBIVA

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

If you notice within 18 hours of the time you usually take ATEBIVA, 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 ATEBIVA, 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 ATEBIVA, take another tablet.

Do not stop taking ATEBIVA

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

When your supply of ATEBIVA 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 ATEBIVA 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 ATEBIVA 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 ATEBIVA, ask your doctor or pharmacist.

4. Possible side effects

ATEBIVA can have side effects.

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

If any of the following happens, stop taking ATEBIVA 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

- 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 ATEBIVA

Store all medicines out of reach of children.

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 ATEBIVA contains

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

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

ATEBIVA 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 ATEBIVA looks like and contents of the pack

ATEBIVA blue, film-coated, rectangular, biconvex, bevelled edge tablet debossed with M on one side of the tablet and EA I on the other side.
ATEBIVA comes in bottles of 30 tablets (with a silica gel desiccant that must be kept in the bottle to help protect your tablets).

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

Holder of Certificate of Registration

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To Be Allocated