BICTEGRAVIR/ EMTRICITABINE/ TENOFOVIR ALAFENAMIDE

Other NAMES: Biktarvy® is a purplish brown tablet that is a combination of bictegravir 50 mg, emtricitabine 200 mg and tenofovir alafenamide 25mg in each tablet.

WHY is this drug prescribed?

This tablet contains bictegravir, an integrase stand transfer inhibitor (INSTI) AND tenofovir alafenamide and emtricitabine, two antiretroviral (anti-HIV) reverse transcriptase inhibitors ("nukes"). It is a convenient single tablet treatment option for HIV infection in adults. By using Biktarvy® consistently, your immune system should improve (increase in CD4+ count) and you will be better protected against infections.

Biktarvy® does not cure AIDS or completely kill the HIV virus, but helps to prevent further damage by slowing down the production of new viruses.

HOW should this drug be taken?

Generally, the dose is 1 tablet once a day, with or without food.

Take Biktarvy® 2 hours before or after antacids or mineral supplements; alternatively, Biktarvy® may be taken together with mineral supplements with food.

What should you do if you FORGET a dose?

If you miss a dose of Biktarvy® and it is less than 18 hours from when you normally take it, take the dose immediately. If it is more than 18 hours from when you normally take Biktarvy®, do not take the dose and wait until your next scheduled dose. Do not take 2 doses of Biktarvy® at the same time, and do not take more than 1 dose in the same day.

Why should you not forget to take this drug?

If you miss doses of this drug, the amount of HIV virus in your blood (known as the viral load) will start increasing again and your immune system will be further damaged. A few missed doses can be enough for the three components: bictegravir, tenofovir alafenamide and emtricitabine, to stop being active, a phenomenon known as **resistance**. When this happens, other antiretrovirals that work in a similar way may also become inactive. Therefore, missing doses of this drug can decrease treatment options for the future. Please do not stop this drug without talking to your doctor first.

What ADVERSE EFFECTS can this drug cause? What should you do about them?

Most common adverse effects reported with Biktarvy® are mild, and include nausea, diarrhea, fatigue, headache, trouble sleeping and abnormal dreams.

Less common side effects include indigestion, bloating, depression, rash and thoughts of suicide. If these effects occur and

are bothersome, please discuss this with your doctor or pharmacist.

Rare but serious adverse effects that have been observed are damage to the liver, especially in patients with long-term hepatitis B or C. This can manifest as jaundice (skin or eyes turn yellow), dark urine and stools and loss of appetite.

If you have hepatitis B and are taking Biktarvy®, do not stop taking the medication without consulting your doctor first. Stopping Biktarvy® may worsen the hepatitis B infection.

It is important that you keep your doctor appointments and come for your laboratory tests so that your progress can be followed.

What other PRECAUTIONS should you follow while using this drug?

You must make sure that you are taking the right dose. If you take higher doses than what is prescribed, you may increase the chance of having side effects. If you take lower doses of than what is prescribed, the HIV virus may become resistant to Biktarvy®.

Certain drugs can increase or decrease the effect of bictegravir, tenofovir alafenamide and emtricitabine. Drugs that interact with Biktarvy® and may alter its effect include:

Anticonvulsants:

Carbamazepine (Tegretol®, Carbatrol®, Epitol®), oxcarbazepine (Trileptal®), phenobarbital and phenytoin (Dilantin®)

• Antimycobacterials:

Rifampin (Rifadin®, Rofact®), Rifabutin (Mycobutin®), Rifapentine (Priftin®)

- Antacids or mineral supplements
 Aluminium hydroxide, magnesium
 hydroxide or calcium carbonate. Take
 Biktarvy® 2 hours before or after
 antacids or mineral supplements;
 alternatively, Biktarvy® may be taken
 together with mineral supplements
 with food.
- Antifungals:

Ketoconazole (Nizoral®), Itraconazole (Sporanox®)

• Antiretrovirals:

Atazanavir (Reyataz®, Evotaz®)

Drugs that should not be taken with Biktarvy® are:

- Other medications containing tenofovir (Atripla®, Complera®, Descovy®, Genvoya®, Odefsey®, Stribild®, Truvada®, Viread®)
- Other medications containing emtricitabine or lamivudine (Atripla®, Complera®, Emtriva®, Descovy®, Genvoya®, Stribild®, Odefsey®, Truvada®, 3TC, Combivir®, Heptovir®, Kivexa®, Triumeq®, Trizivir®)

Inform your doctor and pharmacist of all prescribed and non-prescribed drugs (including vitamins and minerals) you are taking. As well, you should inform them of natural products you are taking. Some products such as St. John's wort influence the effect of Biktarvy® and should not be taken together. If you wish to start a new drug or natural product, please consult with your pharmacist before doing so.

Please inform your doctor if you are pregnant. Your doctor can recommend the appropriate treatment to help to reduce the risk of passing the HIV virus on to your baby. Breastfeeding is **NOT recommended** if you have HIV as you can transmit the virus to your baby through your breast milk.

How should this drug be STORED?

Biktarvy® tablets should be stored in a cool dry place (below 30°C), protected from light and well out of the reach of children. Ensure that the drug has not expired by checking the expiry date ("EXP") shown on the outside of the package. Do not store in your bathroom or kitchen, as heat and moisture may cause the drug to be less active.

If you have any questions or concerns about this drug or if you are experiencing adverse effects, please discuss them with your pharmacist, doctor or nurse.

Write questions or concerns down to ensure they are addressed.

The following pharmacist is available to answer questions:

Pharmacist: _____

Reference: Product Monograph Biktarvy™(bictegravir/ tenofovir alafenamide/emtricitabine). Gilead Canada Inc, Mississauga, ON, 2018.

Prepared by Zubeir Khan (PharmD student 2019).

Additional medication fact sheets and updates may be found at: https://hivclinic.ca

BICTEGRAVIR
+
EMTRICITABINE
+
TENOFOVIR
ALAFENAMIDE

(BIKTARVY®)

MEDICATION

FACT SHEET