Evotaz

WHAT IS EVOTAZ?

Evotaz is a drug used as part of antiretroviral therapy (ART). Evotaz contains two antiretroviral drugs (ARVs) combined in one tablet:

- atazanavir (ATV, Reyataz)
- cobicistat (COBI, Tybost)

The FDA approved Evotaz in 2015 as an ARV for people with HIV infection. Evotaz is manufactured by Bristol Myers Squibb.

One of the drugs in Evotaz, atazanavir, is a type of drug called a protease inhibitor (PI). PIs block protease (an HIV enzyme). By blocking protease, PIs prevent new (immature) HIV from becoming a mature virus that can infect other cells. The other drug, cobicistat, is a type of drug called a pharmacokinetic enhancer (PK enhancer) or CYP3A inhibitor. PK enhancers are used to boost the effectiveness of other drugs. When the two drugs are given together, the PK enhancer interferes with the liver metabolism and breakdown of the other drug, which allows the other drug to remain in the body longer at a higher concentration. PK enhancers are included in some HIV treatment regimens. Cobicistat itself is not an ARV and does not treat HIV.

When used in combination with other ARVs to treat HIV infection, Evotaz may help:

- Reduce the amount of HIV in your blood. This is called viral load.
- Increase the number of CD4 cells in your blood that help fight off other infections.

Reducing the amount of HIV and increasing CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting opportunistic infections (OIs) that can happen when your immune system is weak. Read more about viral suppression.

Evotaz does not cure HIV infection or AIDS. You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

WHO SHOULD TAKE EVOTAZ?

Evotaz is a two-drug fixed-dose combination medication that is used in combination with other ARVs to treat HIV infection in adults and children who weigh at least 77 pounds (35 kg).

The safety and effectiveness of Evotaz has not been established in children who weigh less than 77 pounds (35 kg). Evotaz has not been carefully studied in the elderly (65 years of age and older).

All people living with HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. Read more about U.S. ART guidelines.

Evotaz provides two drugs in one pill. It can be more convenient to use Evotaz than some other combinations of drugs that must be taken separately or at different times of the day. This could mean fewer missed doses and better control of HIV. **Evotaz is used in combination with other ARVs for the treatment of HIV infection.**

WHO SHOULD NOT TAKE EVOTAZ?

Do not take Evotaz if you are allergic to atazanavir, cobicistat, or any of the ingredients in this drug.

Do not take Evotaz if you are taking any of the following medicines. Taking Evotaz with these medicines may affect how Evotaz works. Evotaz may cause serious or life-threatening side effects or death when used with these medicines:

- Alpha 1-adrenoreceptor antagonist: alfuzosin
- Cancer medicine: irinotecan
- Gout medicine: colchicine (if you have liver or kidney problems)
- Antipsychotic medicines: lurasidone, pimozide
- Seizure medicines: carbamazepine, phenobarbital, phenytoin
- Tuberculosis (TB) medicine: rifampin
- Benzodiazepines: midazolam (when taken by mouth), triazolam
- Cholesterol medicines: lomitapide, lovastatin, simvastatin
- Ergot-containing medicines: dihydroergotamine, ergotamine, and methylergonovine

- Heart medicines: dronedarone hydrochloride, ranolazine
- Heartburn and reflux medicines: cisapride
- Hepatitis C virus (HCV) medicines: elbasvir, grazoprevir, glecaprevir, pibrentasvir
- Herbal product: St. John's Wort (*Hypericum perforatum*)
- Hormonal birth control: drospirenone, ethinyl estradiol
- Other ARVs: indinavir, nevirapine
- PDE-5 inhibitor: sildenafil (when used for the treatment of pulmonary arterial hypertension [PAH])

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. If you have taken any of these medicines in the past four weeks, talk to your healthcare provider or pharmacist before starting treatment with Evotaz.

Evotaz is not recommended in people who have taken HIV medicines before who have end-stage renal disease (ESRD) managed with dialysis. Evotaz is not recommended in people with any degree of liver disease.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING EVOTAZ?

Before you take Evotaz, tell your healthcare provider about all of your medical conditions, and in particular if you have:

- Heart problems
- Liver problems, including hepatitis B virus (HBV) infection or HCV infection
- Kidney problems
- Diabetes
- Hemophilia

Talk to your healthcare provider if you are pregnant, you plan to become pregnant, you become pregnant, or think you may be pregnant during treatment with Evotaz. **Evotaz should not be used during pregnancy** because the Evotaz levels in your blood may be lower during pregnancy and may not control your HIV. Your healthcare provider may prescribe different medicines if you become pregnant during treatment with Evotaz. People who are pregnant may develop serious condition called lactic acidosis (a build-up of lactic acid in the blood) when taking Evotaz with other HIV medicines called nucleoside analogues (NRTIs and NNRTIs).

Hormonal forms of birth control, such as injections, vaginal rings or implants, contraceptive patch, and some birth control pills may not work during treatment with Evotaz. Talk to your healthcare provider about forms of birth control that may be used during treatment with Evotaz.

There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry. After your baby is born, tell your healthcare provider if your baby's skin or the white part of their eyes turns yellow. Read more about pregnancy and HIV.

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with Evotaz. You should not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your healthcare provider about the best way to feed your baby.

WHAT ABOUT DRUG RESISTANCE?

Many new copies of HIV are mutations. These new copies are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called developing resistance to the drug. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. Read more about HIV drug resistance.

Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.

HOW IS EVOTAZ TAKEN?

Evotaz is taken by mouth as a tablet. Each Evotaz tablet contains 300 mg of atazanavir and 150 mg of cobicistat. The recommended dosage of Evotaz for adults and children who weigh at least 77 pounds (35 kg) is one tablet once daily.

Take Evotaz at the same time each day with food.

You need to take Evotaz in combination with other ARVs. Your healthcare provider will tell you what medicines to take and how to take them.

WHAT ARE THE SIDE EFFECTS?

When you start any ARV, you may have temporary side effects such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of Evotaz include yellowing of the skin and rash.

Evotaz can cause serious side effects including:

Changes in the way your heart beats (heart rhythm change). Tell your healthcare provider right away if you get dizzy or lightheaded. These could be symptoms of a heart problem.

Skin rash. Skin rash is common with Evotaz but can sometimes be severe. Skin rash usually goes away within 2 weeks without any change in treatment. Severe rash may develop with other symptoms which could be serious. If you develop a severe rash or a rash with any of the following symptoms, stop taking atazanavir and call your healthcare provider or go to the nearest hospital emergency room right away:

- General feeling of discomfort or “flu-like” symptoms
- Fever
- Muscle or joint aches
- Red or inflamed eyes, like “pink eye” (conjunctivitis)
- Blisters
- Mouth sores
- Swelling of your face
- Painful, warm, or red lump under your skin

Kidney problems. Evotaz can cause new or worse kidney problems, including kidney failure. Your healthcare provider will do blood and urine tests to check your kidneys before you start Evotaz and during treatment.

Gallbladder problems. Gallbladder problems have happened in some people who take atazanavir, one of the medicines in Evotaz. Tell your healthcare provider right away if you get symptoms of gallbladder problems, which may include pain in the right or middle upper stomach area, nausea and vomiting, fever, and your skin or the white part of your eyes turns yellow.

Liver problems. If you have liver problems, including HBV or HCV, your liver problems may get worse when you take Evotaz. Your healthcare provider will do blood tests to check your liver before you start Evotaz and during treatment. Tell your healthcare provider right away if you get any of the following symptoms:

- Dark or “tea-colored” urine
- Your skin or the white part of your eyes turns yellow
- Light colored stools (bowel movements)
- Nausea or vomiting
- Itching
- Stomach-area pain

Yellowing of your skin or the white part of your eyes. This is common with Evotaz but may be a symptom of a serious problem. These symptoms may be due to increases in bilirubin levels in your blood (bilirubin is made by the liver). Although these effects may not be damaging to your liver, skin, or eyes, tell your healthcare provider right away if your skin or the white part of your eyes turns yellow.

Immune Reconstitution Inflammatory Syndrome (IRIS). IRIS is a side effect that can happen when you start taking HIV medications. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. This may result in an inflammatory response which may require further evaluation and treatment. Tell your healthcare provider right away if you experience any new symptoms after starting Evotaz.

Diabetes and high blood sugar (hyperglycemia). Some people have had to start taking medicine to treat diabetes or have changes to their dose of diabetes medicine. Tell your healthcare provider if you notice an increase in thirst or if you start urinating more often while taking Evotaz.

Changes in body fat. Changes in body fat distribution or accumulation have happened in some people taking HIV medicines, including an increased amount of fat in the upper back and neck (buffalo hump), in the breasts, and around the trunk. Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these body fat changes are not known.

Increased bleeding for hemophiliacs. Some people with hemophilia have increased bleeding with protease inhibitors including atazanavir.

These are not all the possible side effects of Evotaz. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

HOW DOES EVOTAZ REACT WITH OTHER DRUGS?

All ARVs can interact with other drugs or supplements you are taking. These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take Evotaz with other medicines.

See above for a list of medicines that should not be taken with Evotaz.

Guidelines for taking antacids with atazanavir-containing drugs are complicated. Be sure your healthcare provider knows if you are taking antacids.

MORE INFORMATION

Visit the Evotaz website.

Visit the Evotaz healthcare professional website.

Download the full Prescribing Information.

Download the Patient Information leaflet.

Apply for the Bristol Myers Squibb Patient Support Program.

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