

PATIENT INFORMATION
EVOTAZ® (EV-oh-taz)
(atazanavir and cobicistat) tablet

What is EVOTAZ?

EVOTAZ is a prescription medicine that is used with other human immunodeficiency virus-1 (HIV-1) medicines to treat HIV-1 infection in adults and in children weighing at least 77 pounds (35 kg).

HIV-1 is the virus that causes Acquired Immunodeficiency Syndrome (AIDS).

EVOTAZ contains the prescription medicines atazanavir and cobicistat.

It is not known if EVOTAZ is safe and effective in children weighing less than 77 pounds (35 kg).

Do not take EVOTAZ if you:

- are allergic to any of the ingredients in EVOTAZ. See the end of this leaflet for a complete list of ingredients in EVOTAZ.
- are taking any of the following medicines. Taking EVOTAZ with these medicines may affect how EVOTAZ works. EVOTAZ may cause serious life-threatening side effects, or death when used with these medicines:
 - alfuzosin
 - apalutamide
 - carbamazepine
 - colchicine, if you have liver or kidney problems
 - dronedarone
 - drospirenone and ethinyl estradiol
 - elbasvir and grazoprevir
 - encorafenib
 - ergot-containing medicines, including:
 - dihydroergotamine
 - ergotamine
 - methylergonovine
 - glecaprevir and pibrentasvir
 - indinavir
 - irinotecan
 - ivosidenib
 - lovastatin
 - lomitapide
 - lurasidone
 - midazolam, when taken by mouth for sedation
 - nevirapine
 - phenobarbital
 - phenytoin
 - pimozide
 - ranolazine
 - rifampin
 - sildenafil, when used for the treatment of pulmonary arterial hypertension (PAH)
 - simvastatin
 - St. John's wort (*Hypericum perforatum*), or a product that contains St. John's wort
 - triazolam

Before taking EVOTAZ, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems
- have liver problems, including hepatitis B or C virus
- have kidney problems
- are receiving dialysis treatment
- have diabetes
- have hemophilia
- are pregnant or plan to become pregnant. It is not known if EVOTAZ will harm your unborn baby.
 - **EVOTAZ should not be taken during pregnancy**, because the EVOTAZ levels in your blood may be lower during pregnancy and may not control your HIV-1.
 - Tell your healthcare provider right away if you become pregnant during treatment with EVOTAZ.
 - Your healthcare provider may prescribe different medicines if you become pregnant during treatment with EVOTAZ.
 - People who are pregnant have developed a serious condition called lactic acidosis (a build-up of lactic acid in the blood) when taking EVOTAZ with other HIV-1 medicines called nucleoside analogues.
 - **Hormonal forms of birth control, such as injections, vaginal rings or implants, contraceptive patches, 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.
 - **Pregnancy Exposure Registry.** There is a pregnancy exposure registry for people who take EVOTAZ during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.

- are breastfeeding or plan to breastfeed. EVOTAZ can pass into your breast milk.
 - Talk to your healthcare provider about the following risks to your baby from breastfeeding during treatment with EVOTAZ:
 - The HIV-1 virus may pass to your baby if your baby does not have HIV-1.
 - The HIV-1 virus may become harder to treat if your baby has HIV-1.
 - Your baby may get side effects from EVOTAZ.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medicines interact with EVOTAZ. **Keep a list of your medicines to show your healthcare provider and pharmacist.**

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with EVOTAZ.
- **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take EVOTAZ with other medicines.

How should I take EVOTAZ?

- Take EVOTAZ exactly as your healthcare provider tells you.
- Do not change your dose or stop taking EVOTAZ without talking to your healthcare provider.
- Stay under a healthcare provider's care during treatment with EVOTAZ.
- EVOTAZ must be used with other HIV-1 medicines.
- Take EVOTAZ 1 time a day with food.
- Do not miss a dose of EVOTAZ. If you miss a dose of EVOTAZ, take it as soon as possible. Take your next dose at your normal scheduled time. Do not take 2 doses at the same time to make up for a missed dose.
- When your EVOTAZ supply starts to run low, get more from your healthcare provider or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to EVOTAZ and become harder to treat.
- If you take too much EVOTAZ, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of EVOTAZ?

EVOTAZ can cause serious side effects, including:

- **A change in the way your heart beats (heart rhythm change).** If you have certain heart rhythm problems, your healthcare provider may check your heart rhythm with a test called an electrocardiogram (ECG). Tell your healthcare provider right away if you get dizzy or lightheaded. These could be symptoms of a heart problem.
- **Severe skin reactions.** 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. Call your healthcare provider or go to the nearest hospital emergency room right away if you develop a severe rash or a rash with any of the following symptoms:

◦ general feeling of discomfort or "flu-like" symptoms	◦ red or inflamed eyes, like "pink eye" (conjunctivitis)
◦ fever	◦ blisters
◦ muscle or joint aches	◦ mouth sores
◦ swelling of your face	◦ painful, warm, or red lump under your skin
- **Kidney problems.** EVOTAZ, when taken with certain other medicines, can cause new or worsening kidney problems, including kidney failure. Your healthcare provider should check your kidneys before you start EVOTAZ and during treatment.
- **Chronic kidney disease.** EVOTAZ may affect how well your kidneys work. Your healthcare provider will do blood and urine tests to check your kidneys before you start EVOTAZ and during treatment. Drink plenty of fluids during treatment with EVOTAZ.
- **Kidney stones** have happened in some people who take atazanavir, one of the medicines in EVOTAZ, and sometimes may lead to hospitalization. Tell your healthcare provider right away if you get symptoms of kidney stones, which may include pain in your low back or low stomach area, blood in your urine, or pain when you urinate.
- **Gallbladder stones** have happened in some people who take atazanavir, one of the medicines in EVOTAZ, and sometimes may lead to hospitalization. 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
- fever
- nausea and vomiting
- your skin or the white part of your eyes turns yellow
- **Liver problems.** If you have liver problems, including hepatitis B or C virus, 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:
 - your skin or the white part of your eyes turns yellow
 - dark (tea-colored) urine
 - light colored stools
 - nausea
 - itching
 - stomach-area pain
- **Yellowing of the skin or the white part of your eyes** is common with EVOTAZ but may be a symptom of a serious problem. These effects may be due to increases in bilirubin levels in the blood (bilirubin is made by the liver). Tell your healthcare provider right away if your skin or the white part of your eyes turns yellow.
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider if you start having new symptoms after starting EVOTAZ.
- **Diabetes and high blood sugar (hyperglycemia).** New or worsening diabetes and hyperglycemia have happened in people who take protease inhibitor medicines like EVOTAZ. Some people have had to start taking medicine to treat diabetes or have had to change their diabetes medicine. Tell your healthcare provider if you notice an increase in thirst or if you start urinating more often during treatment with EVOTAZ.
- **Changes in body fat** can happen in people taking HIV-1 medicines. These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms, and face may also happen. The exact cause and long-term health effects of these conditions are not known.
- **Increased bleeding problems in people with hemophilia** have happened when taking protease inhibitors including EVOTAZ.

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

These are not all the possible side effects of EVOTAZ.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store EVOTAZ?

- Store EVOTAZ tablets at room temperature between 68°F and 77°F (20°C and 25°C).
- The EVOTAZ bottle contains a desiccant that helps keep your medicine dry.
- The EVOTAZ bottle has a child-resistant closure.
- Keep tablets in a tightly closed container.

Keep EVOTAZ and all medicines out of the reach of children.

General information about the safe and effective use of EVOTAZ.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use EVOTAZ for a condition for which it was not prescribed. Do not give EVOTAZ to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about EVOTAZ that is written for health professionals.

What are the ingredients in EVOTAZ?

Active ingredients: atazanavir and cobicistat

Inactive ingredients:

Tablet Core: croscarmellose sodium, crospovidone, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, silicon dioxide, sodium starch glycolate, and stearic acid.

Film coat: hypromellose, red iron oxide, talc, titanium dioxide, and triacetin.

Manufactured for:

Bristol-Myers Squibb Company
Princeton, NJ 08543 USA

EVOTAZ is a trademark of Bristol-Myers Squibb Company.

For more information, call 1-800-321-1335.

This Patient Information has been approved by the U.S. Food and Drug Administration

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