

## **PATIENT INFORMATION**

### **EVOTAZ<sup>®</sup> (EV-oh-taz) (atazanavir and cobicistat) tablet**

Read this Patient Information before you start taking EVOTAZ and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

#### **What is EVOTAZ?**

EVOTAZ is a prescription HIV-1 (Human Immunodeficiency Virus) medicine used with other antiretroviral medicines to treat HIV-1 infection in adults. HIV is the virus that causes AIDS (Acquired Immunodeficiency Syndrome).

EVOTAZ contains the prescription medicines REYATAZ<sup>®</sup> (atazanavir) and TYBOST<sup>®</sup> (cobicistat).

It is not known if EVOTAZ is safe and effective in children under 18 years of age.

#### **When used with other antiretroviral medicines to treat HIV-1 infection, EVOTAZ may help:**

- reduce the amount of HIV-1 in your blood. This is called “viral load.”
- increase the number of CD4+ (T) cells in your blood that help to fight off other infections.

Reducing the amount of HIV-1 and increasing the CD4+ (T) cells in your blood may help improve your immune system. This may reduce your risk of death or getting infections that can happen when your immune system is weak (opportunistic infections).

**EVOTAZ does not cure HIV-1 infection or AIDS. You must keep taking HIV-1 medicines to control HIV-1 infection and decrease HIV-related illnesses.**

#### **Avoid doing things that can spread HIV-1 infection to others:**

- Do not share or reuse needles or other injection equipment.
- Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.
- Do not have any kind of sex without protection. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with any body fluids such as semen, vaginal secretions, or blood.

Ask your healthcare provider if you have any questions about how to prevent passing HIV to other people.

## **Who should not take EVOTAZ?**

### **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. EVOTAZ may cause serious life-threatening side effects or death when used with these medicines:
  - alfuzosin (UROXATRAL<sup>®</sup>)
  - carbamazepine (CARBATROL<sup>®</sup>, EPITOL<sup>®</sup>, EQUETRO<sup>®</sup>, TEGRETOL<sup>®</sup>)
  - cisapride (PROPULSID<sup>®</sup>, PROPULSID<sup>®</sup> QUICKSOLV<sup>®</sup>)
  - colchicine (COLCRYS<sup>®</sup>, MITIGARE<sup>™</sup>), if you have liver or kidney problems
  - dronedarone hydrochloride (MULTAQ<sup>®</sup>)
  - drospirenone/ethinyl estradiol (BEYAZ<sup>®</sup>, SAFYRAL<sup>®</sup>, YASMIN<sup>®</sup>, YAZ<sup>®</sup>)
  - elbasvir/grazoprevir (ZEPATIER<sup>®</sup>)
  - ergot-containing medicines:
    - dihydroergotamine mesylate (D.H.E. 45<sup>®</sup>, EMBOLEX<sup>®</sup>, MIGRANAL<sup>®</sup>)
    - ergotamine tartrate (CAFERGOT<sup>®</sup>, MIGERGOT<sup>®</sup>, ERGOMAR<sup>®</sup>, ERGOSTAT<sup>®</sup>, MEDIHALER<sup>®</sup>, WIGRAINE<sup>®</sup>, WIGRETTES<sup>®</sup>)
    - methylergonovine (METHERGINE<sup>®</sup>)
  - glecaprevir/pibrentasvir (MAVYRET<sup>®</sup>)
  - indinavir (CRIXIVAN<sup>®</sup>)
  - irinotecan (CAMPTOSAR<sup>®</sup>)
  - lovastatin (ADVICOR<sup>®</sup>, ALTOPREV<sup>®</sup>, MEVACOR<sup>®</sup>)
  - lurasidone (LATUDA<sup>®</sup>)
  - midazolam (VERSED<sup>®</sup>), when taken by mouth for sedation
  - nevirapine (VIRAMUNE<sup>®</sup>, VIRAMUNE XR<sup>®</sup>)
  - phenobarbital (LUMINAL<sup>®</sup>)
  - phenytoin (DILANTIN<sup>®</sup>, PHENYTEK<sup>®</sup>)
  - pimozide (ORAP<sup>®</sup>)
  - ranolazine (RANEXA<sup>®</sup>)
  - rifampin (RIMACTANE<sup>®</sup>, RIFADIN<sup>®</sup>, RIFATER<sup>®</sup>, RIFAMATE<sup>®</sup>)
  - sildenafil (REVATIO<sup>®</sup>), when used for the treatment of pulmonary arterial hypertension (PAH)
  - simvastatin (ZOCOR<sup>®</sup>, VYTORIN<sup>®</sup>, SIMCOR<sup>®</sup>)
  - St. John's wort (*Hypericum perforatum*), or a product that contains St. John's wort

- triazolam (HALCION®)

### **What should I tell my healthcare provider before taking EVOTAZ?**

#### **Before taking EVOTAZ, tell your healthcare provider if you:**

- have heart problems
- have liver problems, including hepatitis B or C virus infection
- have kidney problems
- have diabetes
- have hemophilia
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if EVOTAZ will harm your unborn baby. Pregnant women have developed a serious condition called lactic acidosis (a build-up of lactic acid in the blood) when taking EVOTAZ with other HIV medicines called nucleoside analogues.
  - **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.
  - **Pregnancy Registry.** There is a pregnancy registry for women who take antiretroviral medicines 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.
  - **After your baby is born,** tell your healthcare provider if your baby's skin or the white part of his/her eyes turns yellow.
- are breastfeeding or plan to breastfeed. Do not breastfeed if you take EVOTAZ.
  - You should not breastfeed if you have HIV because of the risk of passing HIV to your baby.
  - It is not known if EVOTAZ passes into your breast milk.
  - Talk to your healthcare provider about the best way to feed your baby.

**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.
- EVOTAZ must be used with other antiretroviral medicines.
- Take EVOTAZ 1 time a day with food.
- If you miss a dose of EVOTAZ, take the dose as soon as possible and then return to your normal schedule.
- If a dose of EVOTAZ is missed, do not double the next dose.
- 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).** 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, 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
  - swelling of your face
  - red or inflamed eyes, like “pink eye” (conjunctivitis)
  - blisters
  - mouth sores
  - painful, warm, or red lump under your skin
- **Kidney problems.** EVOTAZ, when taken with certain other medicines, can cause new or worse kidney problems, including kidney failure. Your healthcare provider should check your kidneys before you start and while you are taking EVOTAZ.
- **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.
- **Kidney stones** 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 kidney stones, which may include pain in your low back or low stomach area, blood in your urine, or pain when you urinate.

- **Gallbladder disorders** 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
  - 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 infection, 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). 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.
- **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 your HIV-1 medicine.
- **Diabetes and high blood sugar (hyperglycemia)** have happened and worsened in some 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.
- **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 were yellowing of the skin and rash.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of EVOTAZ. For more information ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to the 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).
- Keep tablets in a tightly closed container.

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

### **General information about 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.

If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about EVOTAZ that is written for health professionals.

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

### **What are the ingredients in EVOTAZ?**

**Active ingredients:** atazanavir and cobicistat

**Inactive ingredients:** croscarmellose sodium, crospovidone, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, silicon dioxide, sodium starch glycolate, and stearic acid. The film-coating contains hypromellose, red iron oxide, talc, titanium dioxide, triacetin.

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

Manufactured for:  
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