atazanavir (Reyataz)

WHAT IS ATAZANAVIR?

Atazanavir, also known as atazanavir sulfate or ATV (brand name Reyataz), is a drug used as part of antiretroviral therapy (ART). The FDA approved atazanavir in 2003 as an antiretroviral drug (ARV) for people with HIV infection. Generic versions have been approved under PEPFAR. Atazanavir is manufactured by Bristol Myers Squibb.

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 CD4 cells.

When used in combination with other ARVs to treat HIV infection, atazanavir 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 the 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.

Atazanavir 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 ATAZANAVIR?

Atazanavir is a prescription HIV medicine used in combination with other ARVs to treat HIV infection in adults and children 3 months old and older who weigh at least 11 pounds (5 kg).

The safety and effectiveness of atazanavir has not been established in children under 3 months of age who weigh less than 11 pounds (5 kg). Atazanavir has not been carefully studied in the elderly (65 years of age and older).

All people 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.

WHO SHOULD NOT TAKE ATAZANAVIR?

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

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

- Alpha 1-adrenoreceptor antagonist: alfuzosin
- Cancer medicine: irinotecan
- Anti-psychotic medicines: lurasidone (when atazanavir is used with ritonavir), pimozide
- Tuberculosis (TB) medicine: rifampin
- Benzodiazepines: midazolam (when taken by mouth), triazolam
- Cholesterol medicines: lomitapide, lovastatin, simvastatin
- Ergot-containing medicines: dihydroergotamine, ergonovine, ergonovine ergotamine, methylergonovine
- Heart medicines: amiodarone (when atazanavir is used with ritonavir), quinidine (when atazanavir is used with ritonavir)
- Heartburn and reflux medicine: cisapride
- Hepatitis C virus (HCV) medicines: elbasvir, grazoprevir, glecaprevir, pibrentasvir
- Herbal product: St. John’s Wort (*Hypericum perforatum*)
- 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 atazanavir.

Atazanavir is not recommended in people with severe kidney or liver disease.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING ATAZANAVIR?

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

- Have heart problems
- Have liver problems, including hepatitis B virus (HBV) or HCV infection
- Have phenylketonuria (PKU). The artificial sweetener aspartame in atazanavir oral powder contains phenylalanine, which can be harmful to people with PKU.
- Have kidney problems or are receiving dialysis treatment
- Have diabetes
- Have 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 atazanavir. Atazanavir must be taken with ritonavir during pregnancy. 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 atazanavir. Talk to your healthcare provider about forms of birth control that may be used during treatment with atazanavir.

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. Read more about pregnancy and HIV.

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with atazanavir. Atazanavir can pass to your baby in your breastmilk 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 ATAZANAVIR TAKEN?

Atazanavir is taken by mouth as a capsule or oral powder. The recommended dosage of atazanavir for adults is 300 mg once daily, **in combination with 100 mg of ritonavir (Norvir) once daily.** The recommended dosage of atazanavir for children varies based on the child's weight and age and is given in combination with ritonavir. Your healthcare provider will determine the correct dosage.

For adults who cannot tolerate ritonavir, the recommended dosage is 400 mg by mouth daily, taken as two 200 mg capsules once daily. However, this is not recommended for people who have taken other HIV medications previously and experienced treatment failure. For adults who cannot swallow capsules, atazanavir oral powder is taken once daily along with ritonavir at the same recommended adult dosage as the capsules.

You should take atazanavir at the same time each day with food.

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

Atazanavir is also available in one combination medication. Combination HIV medicines contain two or more HIV medicines from one or more drug classes.

- Atazanavir/cobicistat (Evotaz)

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 atazanavir are nausea, headaches, stomach-area pain, vomiting, trouble sleeping, numbness/tingling/burning of hands or feet, dizziness, muscle pain, diarrhea, depression, and fever.

Atazanavir 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 atazanavir but can sometimes be severe. 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

Liver problems. If you have liver problems, including HBV or HCV infection, your liver problems may get worse when you take atazanavir. Your healthcare provider will do blood tests to check your liver before you start atazanavir 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
- Itching
- Stomach-area pain

Chronic kidney disease. Atazanavir may affect how well your kidneys work. Your healthcare provider will do blood and urine tests to check your kidneys before you start atazanavir and during treatment. Drink plenty of fluids during treatment with atazanavir. Read more about HIV and kidney disease.

Kidney stones. Kidney stones 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. Gallbladder stones sometimes may lead to hospitalization. Tell your healthcare provider right away if you get symptoms of a gallbladder problem which may include:

- Pain in the right or middle upper stomach area
- Nausea and vomiting
- Fever
- Your skin or the white part of your eyes turns yellow

Yellowing of your skin or the white part of your eyes. This is common with atazanavir 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). Tell your healthcare provider right away if your skin or the white part of your eyes turns yellow.

New or worsening 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 atazanavir. Read more about HIV and diabetes.

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 atazanavir.

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 atazanavir. 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 ATAZANAVIR 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 atazanavir with other medicines.

See above for a list of medicines that you should not take with atazanavir.

Make sure your healthcare provider knows if you are taking acid-reducing medications such as H2RA or proton pump inhibitors or other ARVs (efavirenz (Sustiva) or tenofovir DF (Viread). These medications can affect atazanavir levels.

MORE INFORMATION

Visit the Reyataz website

Download the full Prescribing Information

Download the Patient Information leaflet

Download the Instructions for Use

Apply for the Bristol Myers Squibb Patient Support Program

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