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Atazanavir

pronounced as (at a za na' veer)

Why is this medication prescribed?

Atazanavir is used along with other medications to treat human immunodeficiency virus (HIV) infection in adults and children who are at least 3 months of age and weigh at least 22 lb (10 kg). Atazanavir is in a class of medications called protease inhibitors. It works by decreasing the amount of HIV in the blood. Although atazanavir does not cure HIV, it may decrease your chance of developing acquired immunodeficiency syndrome (AIDS) and HIV-related illnesses such as serious infections or cancer. Atazanavir must be given with other medications that treat HIV infection to completely treat the infection. Taking these medications along with practicing safer sex and making other lifestyle changes may decrease the risk of transmitting the HIV virus to other people.

How should this medicine be used?

Atazanavir comes as a capsule and as a powder to take by mouth. Atazanavir capsules are taken with food once a day and may be given with a pharmacokinetic booster (medication given to increase the levels of another drug in the body) such as ritonavir or cobicistat. Atazanavir powder must be taken with food and ritonavir. Take atazanavir at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take atazanavir exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

You will take other medications for HIV while you are taking atazanavir. Your doctor will tell you whether these medications should be taken at the same time as atazanavir, or several hours before or after you take atazanavir. Follow this schedule carefully, and ask your doctor or pharmacist if you have questions about the times you should take your medications.

Swallow the capsules whole; do not split, chew, or open them. If you are unable to swallow the capsules, tell your doctor or pharmacist.

Atazanavir powder may be added to foods such as applesauce or yogurt, or liquids such as water, milk, or infant formula. Mix well, and take all of the mixture right away in order to take the full dose. If mixed with water, eat a snack or meal right away after taking the powder mixture. For infants (older than 3 months of age) unable to drink from a cup, the powder can be mixed with infant formula and given with an oral dosing syringe; do not give the mixture to the infant in a baby bottle. If the mixture is not taken

immediately it must be stored at room temperature and taken within 1 hour. Carefully read the manufacturer's instructions that describe how to mix and take a dose of atazanavir. Be sure to ask your pharmacist or doctor if you have any questions about how to mix or take this medication.

Talk to the doctor about what to do if your baby vomits, spits up, or only takes part of the dose of atazanavir.

Atazanavir controls HIV but does not cure it. Atazanavir does not treat HIV infection alone and must always be given with a complete regimen. It is important that all of the medications prescribed by your doctor to treat HIV infection are taken together so that the medications will continue to work to control the infection. Continue to take atazanavir even if you feel well. Do not stop taking atazanavir without talking to your doctor. When your supply of atazanavir starts to run low, get more from your doctor or pharmacist. If you stop taking atazanavir or skip doses, your condition may become more difficult to treat.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient. Read this information carefully and ask your doctor or pharmacist if you have any questions.

Other uses for this medicine

Atazanavir is also sometimes used to prevent infection in healthcare workers or other people who were accidentally exposed to HIV. Talk to your doctor about the risks of using this medication for your condition.

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking atazanavir,

- tell your doctor and pharmacist if you are allergic to atazanavir, any other medications, or any of the ingredients in atazanavir capsules or powder. Your doctor may tell you not to take atazanavir. Ask your pharmacist for a list of the ingredients.
- tell your doctor if you are taking any of following medications or herbal products: alfuzosin (Uroxatral); cisapride (Propulsid; not available in the US); elbasvir and grazoprevir (Zepatier); ergot alkaloids such as dihydroergotamine (D.H.E. 45, Migranal), ergonovine, ergotamine (Ergomar, in Cafergot, in Migergot), or methylergonovine (Methergine); glecaprevir and pibrentasvir (Mavyret); indinavir (Crixivan); irinotecan (Camptosar); lovastatin (Altoprev); lurasidone (Latuda); midazolam by mouth; nevirapine (Viramune), pimozone (Orap); rifampin (Rimactane, Rifadin, in Rifater, in Rifamate); sildenafil (only Revatio brand used for lung disease); simvastatin (Zocor, in Vytorin); St. John's wort; and triazolam (Halcion). Your doctor will probably tell you not to take atazanavir if you are taking one or more of these medications.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, herbal products, and nutritional supplements you are taking or plan to take. Be sure to mention any of the following: anticoagulants ('blood thinners') such as warfarin (Coumadin, Jantoven); antidepressants ('mood elevators') such as amitriptyline, desipramine (Norpramin), doxepin (Silenor, Zonalon), imipramine (Tofranil, Surmontil), protriptyline (Vivactil), trazodone, and trimipramine (Surmontil); certain antifungals such as itraconazole (Onmel, Sporanox), ketoconazole (Extina, Nizoral, Xolegel), and voriconazole (Vfend); bepridil (Vascor) (not available in the US); beta blockers such as labetalol (Trandate), nadolol (Corgard, in Corzide), and propranolol (Hemangeol, Inderal,

Innopran XL, in Inderide); boceprevir (no longer available in the U.S.; Victrelis); bosentan (Tracleer); buprenorphine (Buprenex, Butrans, in Bunavail, in Suboxone, in Zubsolv); calcium channel blockers such as diltiazem (Cardizem, Cartia, Tiazac, others), felodipine, nicardipine (Cardene), nifedipine (Adalat, Afeditab, Procardia), and verapamil (Calan, Verelan, in Tarka, others); certain cholesterol-lowering medications (statins) such as atorvastatin (Lipitor, in Caduet), and rosuvastatin (Crestor); clarithromycin (Biaxin, in Prevpac); colchicine (Colcrys, Mitigare); digoxin (Lanoxin); fluticasone (Flonase, Flovent, in Advair); medications for irregular heartbeat such as amiodarone (Cordarone, Nexterone, Pacerone), lidocaine (Octocaine, Xylocaine), and quinidine (in Nuedexta); medications that suppress the immune system such as cyclosporine (Gengraf, Neoral, Sandimmune), sirolimus (Rapamune), and tacrolimus (Astagraf, Prograf); other medications for HIV or AIDS including efavirenz (Sustiva, in Atripla), ritonavir (Norvir, in Kaletra, in Viekira Pak), saquinavir (Invirase), and tenofovir (Viread, in Atripla, in Stribild, in Truvada, others); midazolam by injection; paclitaxel (Abraxane, Taxol); certain phosphodiesterase inhibitors (PDE-5 inhibitors) used for erectile dysfunction such as sildenafil (Viagra), tadalafil (Cialis), and vardenafil (Levitra, Staxyn); repaglinide (Prandin, in Prandimet); quetiapine (Seroquel); rifabutin (Mycobutin); salmeterol (Serevent, in Advair); sofosbuvir, velpatasvir, and voxilaprevir (Sovaldi, Epclusa, Vosevi); and tadalafil (Adcirca, Cialis). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with atazanavir, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.

- if you are taking antacids, didanosine delayed-release capsules (Videx EC), or any other buffered medication such as buffered aspirin (Bufferin), take atazanavir 2 hours before or 1 hour after you take the medication. Ask your doctor or pharmacist if you are not sure if any of the medications you are taking are buffered.
- tell your doctor if you are taking a medication for indigestion, heartburn, or ulcers such as cimetidine, esomeprazole (Nexium, in Vimovo), famotidine (Pepcid, in Duexis), lansoprazole (Prevacid, in Prevpac), nizatidine (Axid), omeprazole (Prilosec, in Zegerid), pantoprazole (Protonix), rabeprazole (AcipHex), or ranitidine (Zantac). Your doctor may tell you not to take the medication or to take a lower dose of the medication. If you are to continue taking the medication, your doctor will tell you how much time you should allow between taking the medication and taking atazanavir.
- tell your doctor if you have or have ever had an irregular heartbeat, diabetes or high blood sugar, hemophilia (a condition in which the blood does not clot normally) or any other bleeding disorder, hepatitis (a viral infection of the liver) or any other liver disease, kidney or heart disease.
- tell your doctor if you are pregnant or plan to become pregnant. If you become pregnant while taking atazanavir, call your doctor. You should not breast-feed if you are infected with HIV and are taking atazanavir.
- you should know that atazanavir may decrease the effectiveness of hormonal contraceptives (birth control pills, patches, rings, implants, and injections). Talk to your doctor about methods of birth control that will work for you while you are taking atazanavir.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking atazanavir.
- you should know that you may experience hyperglycemia (increases in your blood sugar) while you are taking this medication, even if you do not already have diabetes. Tell your doctor immediately if you have any of the following symptoms while you are taking atazanavir: extreme thirst, frequent urination, extreme hunger, blurred vision, or weakness. It is very important to call your doctor as soon as you have any of these symptoms, because high blood sugar that is not treated can cause a serious condition called ketoacidosis. Ketoacidosis may become life-threatening if it is not treated at an early stage. Symptoms of ketoacidosis include: dry mouth, nausea and vomiting, shortness of breath, breath that smells fruity, and decreased consciousness.

- you should know that while you are taking atazanavir your body fat may increase or move to different areas of your body such as the back of your neck and upper shoulders ('buffalo hump'), stomach, and breasts. You may lose fat from your arms, legs, face, and buttocks. Talk to your doctor if you notice any of these changes in your body fat.
- if you have phenylketonuria (PKU, an inherited condition in which a special diet must be followed to prevent damage to your brain that can cause severe intellectual disability), you should know that atazanavir oral powder is sweetened with aspartame that forms phenylalanine.
- you should know that while you are taking medications to treat HIV infection, your immune system may get stronger and begin to fight other infections that were already in your body. This may cause you to develop symptoms of those infections. If you have new or worsening symptoms at anytime during your treatment with atazanavir, be sure to tell your doctor.

What special dietary instructions should I follow?

Talk to your doctor about eating grapefruit or drinking grapefruit juice while taking this medicine.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Atazanavir may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- nausea
- vomiting
- stomach pain
- diarrhea
- headache
- depression
- fever
- difficulty falling asleep or staying asleep
- muscle pain
- mild rash
- numbness, burning, pain, or tingling of hands or feet

Some side effects can be serious. If you experience any of the following symptoms, call your doctor immediately or get emergency medical treatment:

- irregular heartbeat
- dizziness

- feeling faint or lightheadedness
- vision changes
- yellowing of skin or eyes (especially in newborn infants)
- pain in your back or side
- pain or burning with urination
- blood in urine
- vomiting
- loss of appetite
- swelling of hands, feet, legs, or ankles
- decreased urination
- dark-colored urine
- light-colored bowel movements
- erection that lasts longer than 4 hours

If you develop a severe rash with any of the following symptoms, stop taking atazanavir and call your doctor immediately or get emergency medical treatment:

- general ill feeling or 'flu-like' symptoms
- fever
- muscle or joint aches
- red or swollen eyes
- blisters or peeling skin
- mouth sores
- swelling of your face or neck
- painful, warm, or red lump under your skin

Atazanavir may cause other side effects. Call your doctor if you have any unusual problems while you are taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container or packet it came in, tightly closed, and out of reach of children and pets. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include the following:

- yellowing of skin or eyes

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests before and during your treatment to check your body's response to atazanavir.

Keep a supply of atazanavir on hand. Do not wait until you run out of medication to refill your prescription.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Reyataz[®]

Other names

- ATZ

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