

PATIENT INFORMATION
Atazanavir (A-ta-ZAN-a-vir)
Capsules

Important: Ask your healthcare provider or pharmacist about medicines that should not be taken with atazanavir capsules. For more information, see “Do not take atazanavir if you” and “Before taking atazanavir capsules”.

What are atazanavir capsules?

Atazanavir capsules are a prescription medicine that is used to treat human immunodeficiency virus-1 (HIV-1) infection, in combination with other HIV-1 medicines in adults and children 6 years of age and older and who weigh at least 15 kg.

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

Atazanavir should not be used in children younger than 3 months of age.

Do not take atazanavir capsules if you:

- are allergic to atazanavir or any of the ingredients in atazanavir capsules. See the end of this leaflet for a complete list of ingredients in atazanavir capsules.
- are taking any of the following medicines. Taking atazanavir capsules with these medicines may affect how atazanavir capsules work. Atazanavir capsules may cause serious or life-threatening side effects, or death when used with these medicines:

<ul style="list-style-type: none"> ○ alfuzosin ○ amiodarone (when atazanavir is used with ritonavir) ○ apalutamide ○ carbamazepine ○ cisapride ○ elbasvir and grazoprevir ○ encorafenib ○ ergot medicines including: <ul style="list-style-type: none"> ▪ dihydroergotamine ▪ ergonovine ▪ ergonovine ergotamine ▪ methylergonovine ○ glecaprevir and pibrentasvir ○ indinavir ○ irinotecan ○ ivosidenib 	<ul style="list-style-type: none"> ○ lurasidone (when atazanavir is used with ritonavir) ○ lomitapide ○ lovastatin ○ midazolam, when taken by mouth for sedation ○ nevirapine ○ phenobarbital ○ phenytoin ○ pimozide ○ quinidine (when atazanavir is used with ritonavir) ○ rifampin ○ sildenafil, when used for the treatment of pulmonary arterial hypertension ○ simvastatin ○ St. John's wort ○ triazolam
---	---

Before taking atazanavir capsules, 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.
 - **Atazanavir capsules 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 capsules.** Talk to your healthcare provider about forms of birth control that may be used during treatment with atazanavir capsules.
 - **Pregnancy Exposure Registry.** There is a pregnancy exposure registry for people who take atazanavir capsules 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 their eyes turns yellow.
- are breastfeeding or plan to breastfeed. Atazanavir capsules can pass into your breast milk.
 - Talk to your healthcare provider about the following risks of breastfeeding during treatment with atazanavir capsules:
 - The HIV-1 virus may pass to your baby if your baby does not have the HIV-1 virus.
 - The HIV-1 virus may become harder to treat if your baby has the HIV-1 virus.
 - Your baby may get side effects from atazanavir capsules.

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 atazanavir capsules. **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 atazanavir capsules.
- **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take atazanavir capsules with other medicines.

How should I take atazanavir capsules?

- **Take atazanavir capsules exactly as your healthcare provider tells you to.**
- Do not change your dose or stop taking atazanavir capsules unless your healthcare provider tells you to.
- Stay under the care of your healthcare provider during treatment with atazanavir capsules.
- Atazanavir capsules must be used with other HIV-1 medicines.
- Take atazanavir capsule 1 time each day.
- Atazanavir comes as capsules.
- Take atazanavir capsules with food.
- Swallow the capsules whole. Do not open the capsules.
- Your child's healthcare provider will prescribe the right dose of atazanavir capsules based on your child's weight.
- If you miss a dose of atazanavir capsules, take it as soon as you remember. Then take the next dose at your regular time. Do not take 2 doses at the same time.
- If you take too many atazanavir capsules, call your healthcare provider or go to the nearest hospital emergency room right away.

When your supply of atazanavir capsules starts to run low, get more from your healthcare provider or pharmacy. It is important not to run out of atazanavir capsules. The amount of HIV-1 in your blood may increase if the medicine is stopped for even a short time. The virus may become resistant to atazanavir capsules and harder to treat.

What are the possible side effects of atazanavir capsules?

Atazanavir capsules 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 atazanavir capsules 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 capsules and call your healthcare provider or go to the nearest hospital emergency room right away:

<ul style="list-style-type: none"> ○ general feeling of discomfort or “flu- like” symptoms ○ fever ○ muscle or joint aches ○ red or inflamed eyes, like “pink eye” (conjunctivitis) 	<ul style="list-style-type: none"> ○ blisters ○ mouth sores ○ swelling of your face ○ painful, warm, or red lump under your skin
---	--
- **Liver problems.** If you have liver problems, including hepatitis B or C virus, your liver problems may get worse when you take atazanavir capsules. Your healthcare provider will do blood tests

to check your liver before you start atazanavir capsules and during treatment. Tell your healthcare provider right away if you get any of the following symptoms:

- dark “tea-colored” urine
- your skin or the white part of your eyes turns yellow
- light colored stools
- nausea
- itching
- stomach-area pain

- **Chronic kidney disease.** Atazanavir capsules may affect how well your kidneys work. Your healthcare provider will do blood and urine tests to check your kidneys before you start atazanavir capsules and during treatment. Drink plenty of fluids during treatment with atazanavir capsules.
- **Kidney stones** have happened in some people who take atazanavir capsules, 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 capsules, and 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
 - your skin or the white part of your eyes turns yellow
 - fever
- **Yellowing of your skin or the white part of your eyes** is common with atazanavir capsules 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)** have happened in some people who take protease inhibitor medicines like atazanavir capsules. Some people have had to start taking medicine to treat diabetes or have changes to their dose of their diabetes medicine. Tell your healthcare provider if you notice an increase in thirst or if you start urinating more often while taking atazanavir capsules.
- **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 atazanavir capsules.
- **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 main part 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 like atazanavir capsules.

The most common side effects of atazanavir capsules include:

- nausea
- headache
- stomach-area pain
- vomiting
- trouble sleeping
- numbness, tingling, or burning of hands or feet
- dizziness
- muscle pain
- diarrhea
- depression
- fever

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 atazanavir capsules. For more information, ask your healthcare provider or pharmacist.

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 atazanavir capsules?

- Store atazanavir capsules at room temperature, between 68°F to 77°F (20°C to 25°C).

- Keep capsules in a tightly closed container.
- The atazanavir capsules bottle comes with a child-resistant closure.

Keep atazanavir capsules and all medicines out of the reach of children.

General information about the safe and effective use of atazanavir capsules

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use atazanavir capsules for a condition for which they were not prescribed. Do not give atazanavir capsules 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 atazanavir capsules that is written for health professionals.

For more information, call Laurus Generics Inc. at 1-833-3-LAURUS (1-833-352-8787).

What are the ingredients in atazanavir capsules?

Active ingredient: atazanavir sulfate USP

Inactive ingredients: crospovidone, lactose monohydrate, and magnesium stearate. The capsule shells contain the following inactive ingredients: gelatin, FD&C Blue No. 2, FD & C Yellow 6, iron oxide yellow, and titanium dioxide. The capsules are printed with ink containing butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, shellac, strong ammonia solution, and titanium dioxide.

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

Brands listed are the trademarks of their respective owners and are not trademarks of Laurus Labs Limited.

Manufactured for:
Laurus Generics Inc.
400 Connell Drive
Suite 5200
Berkeley Heights, NJ 07922

Manufactured by:
Laurus Labs Limited
Anakapalli-531011
India

Revised: 1/2025