

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS’ REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Atazanavir Teva 150 mg Capsules

Composition:

Each capsule contains:

Atazanavir (as sulfate) 150 mg

Atazanavir Teva 200 mg Capsules

Composition:

Each capsule contains:

Atazanavir (as sulfate) 200 mg

Atazanavir Teva 300 mg Capsules

Composition:

Each capsule contains:

Atazanavir (as sulfate) 300 mg

For information regarding inactive ingredients and allergens, see section 2 - “Important information about some ingredients of the medicine” and section 6 - “Additional information”.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is intended for adults and children above 6 years of age. This medicine is not intended for babies under three months of age.

1. What is the medicine intended for?

Atazanavir Teva is intended for treatment of HIV-1 (Human Immunodeficiency Virus type 1) and is given in combination with other antiretroviral medicines intended to treat HIV-1 (antiretroviral agents) in adults and children above 6 years of age.

Atazanavir Teva is not intended for babies under three months of age.

Therapeutic class: Protease inhibitors.

Atazanavir Teva is a prescription medicine against HIV-1 (Human Immunodeficiency Virus type 1), which is given in combination with other antiretroviral medicines intended to treat HIV-1 infections.

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

When used with other antiretroviral medicines to treat HIV-1 infection, Atazanavir Teva may help reduce the amount of the HIV-1 virus in the blood (also called viral load), and to increase the number of CD4+ (T) cells in the blood that help fight off other infections.

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

Atazanavir Teva does not cure HIV-1 infection and does not cure AIDS. Be sure to take the HIV-1 medicines to control HIV-1 infection and decrease other HIV-related illnesses.

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to atazanavir sulfate or to any of the other components the medicine contains (see section 6).
- You are taking any of the following medicines. Taking atazanavir Teva together with the following medicines may affect its activity. Atazanavir Teva may cause serious life-threatening side effects or death when used together with the following medicines:
 - Alfuzosin
 - Amiodarone (in combination with ritonavir), quinidine (in combination with ritonavir)

- Rifampin
- Irinotecan
- Lurasidone (in combination with ritonavir), pimozide
- Triazolam, midazolam (when taken orally)
- Ergot medicines including: dihydroergotamine, ergotamine, ergonovine, methylergonovine
- Cisapride
- Elbasvir/grazoprevir, glecaprevir/pibrentasvir
- Hypericum perforatum (St. John’s wort)
- Lovastatin, simvastatin, lomitapide
- Sildenafil for the treatment of pulmonary arterial hypertension
 - Indinavir
 - Nevirapine

Serious problems may occur if you or your child take any of the medicines listed above together with Atazanavir Teva.

Special warnings regarding the use of the medicine

Before treatment with Atazanavir Teva, inform the doctor if:

- You have heart problems.
- You have impaired liver function, including hepatitis B or C viral infection.
- You have kidney problems.
- You are undergoing dialysis treatment.
- You have diabetes.
- You have hemophilia.
- You are pregnant or planning to become pregnant.
 - During pregnancy you should take Atazanavir Teva together with ritonavir.
- Hormonal contraceptives, such as injections, an intrauterine device or a vaginal ring, a transdermal contraceptive patch and birth control pills may not work during treatment with Atazanavir Teva.** Consult the doctor about contraceptives that may be used during treatment with Atazanavir Teva.
- After your baby is born**, tell the doctor if his skin or the white part of his eyes turns yellow.
- You are breastfeeding or are planning to breastfeed.
 - You should not breastfeed if you have HIV-1, due to the risk of transmitting the virus to your baby. Atazanavir Teva may pass into breastmilk.
 - Consult the doctor regarding the best way to feed your baby.

Tests and follow-up:

Your doctor will do blood tests to check your liver function before you start taking Atazanavir Teva and during treatment.

Your doctor will do blood and urine tests to check your kidney function before you start taking Atazanavir Teva and during treatment.

Children and adolescents:

This medicine is not intended for children under 6 years of age.

This medicine is not intended for babies under three months of age.

Drug interactions:

If you are taking, or have recently taken, other medicines including nonprescription medicines and nutritional supplements, tell the doctor or pharmacist, in order to prevent risks or lack of efficacy resulting from drug interactions.

Keep the list of medicines you are taking in order to present it to the attending doctor and pharmacist. Consult the doctor or pharmacist regarding the list of medicines that interact with Atazanavir Teva. **Do not take a new medicine without first consulting your attending doctor.** The attending doctor can advise you whether taking other medicines together with Atazanavir Teva is safe.

Use of the following medicines together with Atazanavir Teva (with or without ritonavir) may require an adjustment in the dosage or dosing regimen of Atazanavir Teva or of the medicines listed below. Consult the attending doctor if you are taking one or more of the following medicines:

- Medicines to treat HIV such as: didanosine,

tenofovir disoproxil fumarate, efavirenz, nevirapine, saquinavir, indinavir, ritonavir.

- Medicines for treating hepatitis C: Elbasvir/grazoprevir, glecaprevir/pibrentasvir, sofosbuvir/velpatasvir/voxilaprevir.
- Alfuzosin.
- Antacids.
- Medicines to treat heart rate disturbances: amiodarone, quinidine, bepridil, lidocaine (systemically administered).
- Anticoagulants: warfarin, betrixaban, dabigatran, edoxaban, rivaroxaban, apixaban.
- Antidepressants such as: tricyclic antidepressants, trazodone.
- Anticonvulsants to treat epilepsy such as: carbamazepine, phenytoin, phenobarbital, lamotrigine.
- Antifungals such as: ketoconazole, itraconazole, voriconazole.
- Colchicine - to prevent or treat gout.
- Antibiotics: rifabutin, rifampin.
- Irinotecan – used for treatment of metastatic cancer.
- Antipsychotics: pimozide, quetiapine and lurasidone.
- Benzodiazepines: midazolam (parenterally administered), triazolam and midazolam (when taken orally).
- Calcium channel blockers such as: diltiazem, felodipine, nifedipine, nicardipine, verapamil.
- Bosentan - to treat pulmonary hypertension.
- Ergot medicines including: dihydroergotamine, ergotamine, ergonovine, methylergonovine.
- Cisapride - a medicine that affects the motility of the digestive system.
- Hypericum perforatum (St. John’s wort).
- Cholesterol-lowering medicines of the HMG-CoA reductase inhibitors group: lovastatin, simvastatin, atorvastatin, rosuvastatin.
- Other medicines for lowering cholesterol: lomitapide.
- Hormonal contraceptives (pills) – ethinylestradiol, norgestimate or norethindrone.
- Immunosuppressants - ciclosporin, sirolimus, tacrolimus.
- Salmeterol (inhaled).
- Fluticasone - a nasal spray or inhaled steroid.
- Clarithromycin - a macrolide antibiotic.
- Opioid analgesics: buprenorphine.
- Medicines to treat pulmonary arterial hypertension or to treat impotence - sildenafil, tadalafil, vardenafil.
- Omeprazole - proton pump inhibitor.

Use of the medicine and food:

Take the medicine whole with food. No information is available regarding opening the capsules and spreading their contents.

Pregnancy and breastfeeding:

- Before treatment with Atazanavir Teva, tell the doctor if you are pregnant or planning to become pregnant. Consult the attending doctor about taking Atazanavir Teva during pregnancy or if you are planning a pregnancy.
- Hormonal contraceptives, such as injections, an intrauterine device or a vaginal ring, a transdermal contraceptive patch and birth control pills may not work during treatment with Atazanavir Teva. Consult the doctor about contraceptives that may be used during treatment with the preparation.
- After your baby is born, tell the doctor if his skin or the white part of his eyes turns yellow.

Do not breastfeed if you are taking Atazanavir Teva, due to risk of transmitting HIV-1 to your baby. Atazanavir Teva may pass to the baby through the breast milk. Consult the doctor regarding the best way to feed your baby.

Driving and operating machinery:

If you feel dizzy, refer to your doctor immediately.

Important information about some ingredients of the medicine:

Atazanavir Teva contains lactose. If you have been told by the doctor that you have an intolerance (sensitivity) to certain sugars, consult your doctor before taking this medicine.

Atazanavir Teva 150 mg: each capsule contains about 67.2 mg lactose monohydrate.

Atazanavir Teva 200 mg: each capsule contains about 89.6 mg lactose monohydrate.

Atazanavir Teva 300 mg: each capsule contains about 134.4 mg lactose monohydrate.

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The dosage and treatment regimen will be determined only by the doctor.

Atazanavir Teva must be taken in combination with other antiretroviral medicines.

Take the medicine at a set time every day, as instructed by the doctor. Take the medicine according to the dosage and time period determined by the doctor.

Do not exceed the recommended dose.

Take the medicine whole with food. No information is available regarding opening the capsules and spreading their contents.

Do not stop treatment or change the dosage unless the attending doctor tells you to. Follow the treatment as recommended by the doctor.

It is important to be under the attending doctor's care throughout the period of treatment with Atazanavir Teva.

Always make sure that you have an adequate amount of Atazanavir Teva with you, so you will never be without the medicine. If you stop taking the medicine, even for a short time, the amount of the HIV-1 virus in your blood may increase. The virus may become resistant to Atazanavir Teva and as a result, become more difficult to treat.

If you accidentally took a higher dose or if a child accidentally swallowed the medicine, immediately contact a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forget to take this medicine at the required time, take a dose as soon as you remember and take the next dose at the usual time. Do not take a double dose instead of the forgotten dose.

Follow the treatment as recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Atazanavir Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Atazanavir Teva can cause serious side effects. Refer to a doctor in the following cases:

- Changes in heart rhythm.** Refer to a doctor immediately if you feel dizzy. This effect could indicate a heart problem.
- Skin rash.** Skin rash is common in patients taking Atazanavir Teva, but can sometimes be severe. Rash may be accompanied by other serious symptoms and could be severe. If you develop a severe rash or a rash with any of the following symptoms, stop treatment with Atazanavir Teva and refer to the doctor or the nearest hospital immediately:
 - General feeling of sickness or flu-like symptoms
 - Fever
 - Muscle or joint aches
 - Red or inflamed eyes (conjunctivitis)
 - Blisters
 - Mouth sores
 - Swelling of the face
 - Painful, warm or red lump under the skin
- Liver problems.** If you have liver problems, including hepatitis B or C, they may get worse during the course of treatment with Atazanavir Teva. Your doctor will do blood tests to check your liver function before you start taking Atazanavir Teva and during treatment. Inform the doctor immediately if you develop any of the following symptoms:
 - Dark (tea-colored) urine

- Your skin or the white part of your eyes turns yellow
- Pale stools
- Nausea
- Itching
- Pain in the stomach area

- Chronic kidney disease.** Atazanavir Teva may affect your kidney function. Your doctor will do blood and urine tests to check your kidney function before you start taking Atazanavir Teva and during treatment. You should drink a lot during treatment with Atazanavir Teva.
- Kidney stones** have been reported in some patients taking Atazanavir Teva. In some cases the patient was hospitalized. Tell your doctor immediately if you experience symptoms of kidney stones which may include: pain in the lower back or lower stomach area, blood in the urine, or pain when urinating.
- Gallbladder stones** have been reported in some patients taking Atazanavir Teva. In some cases the patient was hospitalized. Tell your doctor immediately if you experience symptoms of gallbladder problems which may include: pain in the right or middle upper stomach area, fever, nausea and vomiting, yellowing of the skin or the white part of the eyes.
- Yellowing of the skin or the white part of the eyes** is a common effect in patients taking Atazanavir Teva, which may sometimes be a symptom of a serious problem. This effect may be due to an increase in bilirubin levels in the blood (bilirubin is produced by the liver). Refer to the doctor immediately if your skin or the white part of the eyes becomes yellow.
- Diabetes or high sugar levels (hyperglycemia)** have been reported or have worsened in some patients taking protease inhibitor medicines such as Atazanavir Teva. Some patients had to start taking medicines to treat diabetes or change the dosage of their diabetes medicinal treatment. Inform your doctor if you feel increased thirst or increased urinary frequency during treatment with Atazanavir Teva.
- Changes in the immune system (Immune Reconstitution Syndrome)** may develop in patients who have started taking medicines for treatment of HIV-1. Your immune system may get stronger and begin to fight previously dormant infections in your body. Tell the doctor if you experience new symptoms after starting to take Atazanavir Teva.
- Changes in body fat** can happen in patients taking HIV-1 medicines. These changes can include an increased amount of fat in the upper back and neck, breast, and around the body trunk. You may experience loss of fat from the legs, arms, and face. The exact cause and long-term health effect of these conditions are not known.
- Increased bleeding in hemophilia patients** has been reported during treatment with protease inhibitors such as Atazanavir Teva.

The most common side effects during treatment with Atazanavir Teva include:

- Nausea
- Headache
- Pain in the abdomen area
- Vomiting
- Sleeping difficulties
- Numbness, tingling, sensation of burning in the hands or feet
- Dizziness
- Muscle pain
- Diarrhea
- Depression
- Fever

A blister pack contains 60 capsules.

A blister pack contains 30 capsules.

A blister pack contains 30, 60 or 90 capsules. Not all package sizes may be marketed.

License holder and address: Abic Marketing Ltd., P.O. box 8077, Netanya.

Manufacturer and address: Teva Pharmaceutical Industries Ltd., P.O. box 3190, Petah Tikva.

Registration numbers of the medicines in the National Drug Registry of the Ministry of Health: Atazanavir Teva 150 mg: 160.95.35017

Atazanavir Teva 200 mg: 160.96.35018

Atazanavir Teva 300 mg: 160.97.35019

The leaflet was revised in May 2021 in accordance with the Ministry of Health guidelines.

This is **not** a full list of side effects of Atazanavir Teva. For further information, refer to the attending doctor or pharmacist.

Reporting side effects Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il),

which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

The medicine should be stored below 25°C.

Atazanavir Teva 150 and 200 mg:

Shelf life after opening the bottle for the first time - 3 months, but no later than the expiry date stated on the package.

Atazanavir Teva 300 mg:

Shelf life after opening the bottle for the first time - 2 months, but no later than the expiry date stated on the package.

Do not discard medicines in wastewater or domestic trash. Ask your pharmacist how to discard medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient the medicine also contains:

Capsule contents:

Lactose monohydrate, crospovidone type A, magnesium stearate.

Capsule body:

Gelatin, titanium dioxide (E171), Indigotine (FD&C Blue No. 2).

In addition, the body of the 300 mg capsule contains: Red iron oxide (E172) and yellow iron oxide (E172). Printing ink:

Shellac glaze, iron oxide black, n-butyl alcohol, purified water, propylene glycol, dehydrated ethanol, isopropyl alcohol, ammonia solution.

What does the medicine look like and what are the contents of the package:

Atazanavir Teva 150 mg:

Opaque capsule. The cap of the capsule is dark blue. The body of the capsule is light blue. The marking 150 appears upon the capsule in black.

The bottle pack contains 60 capsules.

A blister pack contains 60 capsules.

Atazanavir Teva 200 mg:

Opaque capsule. The cap of the capsule is blue. The body of the capsule is blue. The marking 200 appears upon the capsule in black.

The bottle pack contains 60 capsules.

A blister pack contains 60 capsules.

Atazanavir Teva 300 mg:

Opaque capsule. The cap of the capsule is red. The body of the capsule is blue. The marking 300 appears upon the capsule in black.

The bottle pack contains 30 capsules.

A blister pack contains 30, 60 or 90 capsules.

Not all package sizes may be marketed.

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ATAZANAVIR PIL MW6021