

Atazor-300 (Atazanavir Capsules 300mg)

Atazanavir Sulfate equivalent to Atazanavir 300mg

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What Atazor Capsules is used for

Atazor is a prescription medicine used with other anti-HIV medicines to treat people who are infected with the human immunodeficiency virus (HIV).

How Atazor Capsules works

Atazor is a type of anti-HIV medicine called a protease inhibitor. HIV infection destroys CD4+ (T) cells, which are important to the immune system. The immune system helps fight infection. After a large number of (T) cells are destroyed, AIDS develops. Atazor helps to block HIV protease, an enzyme that is needed for the HIV virus to multiply. Atazor may lower the amount of HIV in your blood, help your body keep its supply of CD4+(T) cells, and reduce the risk of death and illness associated with HIV.

Before you use Atazor Capsules

- When you must not use it

Do not take Atazor if you:

- are taking certain medicines. (See 'Taking other medicines') Serious life threatening side effects or death may happen. Before you take Atazor, tell your health care provider about all medicines you are taking or planning to take. These include other prescription and nonprescription medicines, vitamins, and herbal supplements.
- are allergic to Atazor or to any of its ingredients. The active ingredient is atazanavir sulfate. See the end of this leaflet for a complete list of ingredients in Atazor. Tell your healthcare provider if you think you have had an allergic reaction to any of these ingredients.

Pregnancy and lactation

• **If you are pregnant or planning to become pregnant.** It is not known if Atazor can harm your unborn baby. Talk to your healthcare provider about the use of Atazor while you are pregnant.

• **If you are breast-feeding.** You should not breast-feed if you are HIV-positive because of the chance of passing HIV to your baby. Also, it is not known if Atazor can pass into your breast milk and if it can harm your baby. If you are a woman who has or will have a baby, talk with your healthcare provider about the best way to feed your baby.

- Before you start to use it

Do not take Atazor if you take the following medicines (not all brands may be listed; tell your healthcare provider about all the medicines you take).

Atazor may cause serious, life threatening side effects or death when used with these medicines.

- Ergot medicines: dihydroergotamine, ergonovine, ergotamine & methylegonovine
- Triazolam, used for insomnia.
- Midazolam, used for sedation when taken by mouth.
- Pimozide, used for Tourette's disorder.
- Cisapride, used for certain stomach problems.

- Taking other medicines

Do not take the following medicines with Atazor (atazanavir sulfate) because of possible serious side effects:

- Irinotecan, used for cancer.
 - Indinavir, used for HIV infection.
- Both atazanavir sulfate and indinavir sometimes cause increased levels of bilirubin in the blood.
- Cholesterol-lowering medicines eg. lovastatin or simvastatin.

Do not take the following medicines with Atazor because they may lower the amount of Atazor in your blood.

This may lead to an increased HIV viral load. Resistance to Atazor or cross resistance to other HIV medicines may develop:

- Rifampicin, used for tuberculosis.

- St. John's wort (Hypericum perforatum), a herbal product sold as a dietary supplement, or products containing St. John's wort.
- Nevirapine used for HIV infection

Do not take the following medicine if you are taking Atazor and ritonavir together.

- Voriconazole.

The following medicines may require your healthcare provider to monitor your therapy more closely:

- Tadalafil, vardenafil, or sildenafil. Atazor may increase the chances or serious side effects that can happen with tadalafil, vardenafil, or sildenafil. Do not use tadalafil, vardenafil, or sildenafil while you are taking Atazor unless your healthcare provider tells you it is okay.
- Atorvastatin. There is an increased chance or serious side effects if you take Atazor with these cholesterol lowering medicines.
- Medicines for abnormal heart rhythm:
 - Amiodarone, lidocaine & quinidine
 - Bepridil, used for chest pain.
 - Warfarin.
- Medicines to prevent organ transplant rejection: cyclosporin, sirolimus, or tacrolimus.
- Fluticasone propionate, given by nose or inhaled to treat allergic symptoms or asthma. Your doctor may choose not to keep you on fluticasone, especially if you are also taking ritonavir.

How to use Atazor Capsules

How much to use

• **Take Atazor once every day exactly as instructed by your healthcare provider.** Your healthcare provider will prescribe the amount of Atazor that is right for you.

- For adults, the dose is 300 mg once daily with 100 mg of ritonavir once daily taken with food.

Your dose will depend on your liver function and on the other anti-HIV medicines that you are taking. Atazor is always used with other anti-HIV medicines.

• **Always take Atazor with food** (a meal or snack) to help it work better. Swallow the capsules whole. **Do not open the capsules.** Take Atazor at the same time each day.

• If you are taking antacids or didanosine, take Atazor 2 hours before or 1 hour after these medicines.

• If you are taking medicines for indigestion, heartburn, or ulcers such as omeprazole, talk to your healthcare provider.

• Do not change your dose or stop taking Atazor without first talking with your healthcare provider. It is important to stay under a healthcare provider's care while taking Atazor.

• When your supply of Atazor starts to run low, get more from your healthcare provider or pharmacy. It is important not to run out of Atazor. The amount of HIV in your blood may increase if the medicine is stopped for even a short time.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Atazor for as long as your doctor recommends.

- If you forget to use it

• If you miss a dose of Atazor, take it as soon as possible and then take your next scheduled dose at its regular time. If, however, it is within 6 hours of your next dose, do not take the missed dose. Wait and take the next dose at the regular time. Do not double the next dose. It is important that you do not miss any doses of Atazor or your other anti-HIV medicines.

- If you use too much (overdose)

• If you take more than the prescribed dose of Atazor, call your healthcare provider or poison control center right away.

While you are using it

- Things you must do

Tell your healthcare provider:

• **If you are pregnant or planning to become pregnant.** It is not known if Atazor can harm your unborn baby. Talk to your healthcare provider about the use of Atazor while you are pregnant.

• **If you are breast-feeding.** You should not breast-feed if you are HIV-positive because of the chance of

passing HIV to your baby. Also, it is not known if Atazor can pass into your breast milk and if it can harm your baby. If you are a woman who has or will have a baby, talk with your healthcare provider about the best way to feed your baby.

• **If you have liver problems or are infected with the hepatitis B & C virus.**

• **If you have end stage kidney disease managed with hemodialysis.**

• **If you have diabetes.**

• **If you have hemophilia.**

• **About all the medicines you take** including prescription and nonprescription medicines, vitamins, and herbal supplements.

Keep a list of your medicines with you to show your healthcare provider. For more information, see "Taking other medicines" and "Before you use Atazor Capsules". Some medicines can cause serious side effects if taken with Atazor.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Atazor to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

The following list of side effects is not complete. Report any new or continuing symptoms to your healthcare provider. If you have questions about side effects, ask your healthcare provider. Your healthcare provider may be able to help you manage these side effects.

The following side effects have been reported with Atazor:

• **mild rash** (redness and itching).

• **severe rash:** In a small number of patients, a rash can develop that is associated with other symptoms which could be serious and potentially cause death.

If you develop a rash with any of the following symptoms, stop using atazanavir and call your healthcare provider right away:

• shortness of breath

• general ill feeling or "flu-like" symptoms

• fever

• muscle or joint aches

• conjunctivitis (red or inflamed eyes, like "pinkeye")

• blisters

• mouth sores

• swelling of your face

• yellowing of the skin or eyes. These effects may be due to increases in bilirubin levels in the blood (bilirubin is made by the liver). Call your healthcare provider if your skin or the white part of your eyes turns yellow. Although these effects may not be damaging to your liver, skin, or eyes, it is important to tell your healthcare provider promptly if they occur.

• a change in the way your heart beats (heart rhythm change). Call your healthcare provider right away if you get dizzy or lightheaded. These could be symptoms of a heart problem.

• diabetes and high blood sugar (hyperglycemia) sometimes happen in patients taking protease inhibitors medicines like Atazor. Some patients had diabetes before taking protease inhibitors while others did not. Some patients may need changes in their diabetes medicine.

• If you have liver disease including hepatitis B or C, your liver disease may get worse when you take anti-HIV medicines like Atazor (atazanavir sulfate)

• kidney stones have been reported in patients taking atazanavir. If you develop signs or symptoms of kidney stones (pain in your side, blood in your urine, pain when you urinate tell your healthcare provider promptly.

• some patients with hemophilia have increased bleeding problems with protease inhibitors like Atazor.

• changes in body fat. These changes may include an increased amount of fat

in the upper back and neck ("buffalo hump"), breast, 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 conditions are not known at this time.

Other common side effects of Atazor taken with other anti-HIV medicines include nausea; headache; stomach pain; vomiting; diarrhea; depression; fever; dizziness; trouble sleeping; numbness, tingling, or burning of hands or feet; and muscle pain.

Gallbladder disorders (which may include gallstones and gallbladder inflammation) have been reported in patients taking atazanavir.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Atazor Capsules

- Storage
Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Atazor 300: Size 00 hard gelatin capsules, grey cap with 'ATV 300' printed in white and white body with 'ATV 300' printed in black, filled with white to light yellow granules which may appear as powder.

- Ingredients

- Active ingredient
Atazanavir Sulfate equivalent to Atazanavir 300mg

- Inactive ingredients
Crospovidone
Lactose monohydrate
Magnesium stearate

Gelatin
Iron oxide black
Titanium dioxide.

- MAL number:
MAL15045142AZ

Manufacturer

Emcure Pharmaceuticals Ltd.
Plot No. P1 and P2, I.T.B.T. Park
Phase-II, M.I.D.C. Hinjawadi,
Pune 411057, Maharashtra State, India.

Product Registration Holder

Medispec (M) Sdn Bhd
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