

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr Mylan-Atazanavir

atazanavir sulfate capsules

Read this carefully before you start taking **Mylan-Atazanavir** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Mylan-Atazanavir**.

What is Mylan-Atazanavir used for?

Mylan-Atazanavir is used in combination with other antiviral drugs to treat human immunodeficiency virus (HIV) infection in adults and pediatric patients 6 years of age and older and weighing at least 20 kg. HIV is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).

How does Mylan-Atazanavir work?

HIV destroys CD4+ (T) cells. These cells are important to help the immune system fight infection. After a large number of T cells are destroyed, AIDS develops. Mylan-Atazanavir belongs to a family of medicines called protease inhibitors. These help control HIV infection by blocking HIV protease, an enzyme that HIV needs to multiply. This lowers the amount of HIV in your blood (called “viral load”) and allows the number of T cells in your body to increase. Mylan-Atazanavir does not cure HIV infection or AIDS. You may continue to develop infections or other conditions associated with HIV infection. Because of this, it is very important for you to remain under the care of a healthcare professional while taking Mylan-Atazanavir.

What are the ingredients in Mylan-Atazanavir?

Medicinal ingredients: Each capsule contains amounts of atazanavir sulfate corresponding to 150, 200 and 300 mg of atazanavir free base.

Non-medicinal ingredients: The non-medicinal ingredients include Crospovidone, lactose monohydrate, magnesium stearate. Capsule shell: D&C Red 28 (150 mg), FD&C Blue 1 (all strengths), FD&C Red 3 (all strengths), gelatin (all strengths), iron oxide yellow (150 mg and 300 mg), iron oxide red (300 mg) and titanium dioxide (all strengths). Black imprinting ink: black iron oxide, potassium hydroxide, propylene glycol, shellac, strong ammonia solution.

Mylan-Atazanavir comes in the following dosage forms:

Capsules for oral use.

Do not use Mylan-Atazanavir if:

- you are taking any medication listed in this leaflet in the [Serious Drug Interactions box below](#)
- you are allergic to atazanavir sulfate or any of the other ingredients in Mylan-Atazanavir
- you have or have had severe liver disease

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Mylan-Atazanavir. Talk about any health conditions or problems you may have, including if you:

- have liver problems, including Hepatitis B or C infection because the dose of Mylan-Atazanavir may need to be reduced.
- Have kidney problems.
- have or have had heart problems including a slow heartbeat or a genetic condition called “long congenital QT syndrome”.
- Have problems with your electrolytes (low levels of potassium, magnesium or calcium in your blood) or suffer from excessive vomiting or diarrhea.
- have hemophilia Type A or B.
- have lactic acidosis (high levels of acid in the blood). See the [Serious side effects and what to do about them](#) table below for symptoms. Talk to your healthcare professional right away if you get these symptoms.
- are taking quetiapine (SEROQUEL*, SEROQUEL* XR), a medicine used to treat mental health problems such as schizophrenia. Serious side effects that could result in death have happened in patients taking quetiapine together with HIV protease inhibitors.
- are lactose intolerant or have one of the following rare hereditary diseases:
 - o Galactose intolerance,
 - o Lapp lactase deficiency, or
 - o Glucose-galactose malabsorption,

because lactose is a non-medicinal ingredient in Mylan-Atazanavir.

Other warnings you should know about:

Mylan-Atazanavir can cause serious side effects:

- **Gallbladder problems:** Gallstones and gallbladder inflammation have been reported.
- **Heart problems:** Mylan-Atazanavir can cause changes in the way your heart beats (heart rhythm changes).
- **Immune reconstitution inflammatory syndrome:** Changes to your immune system can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Autoimmune disorders can also happen. This is when the immune system attacks healthy body tissue. Examples of this include Grave's disease (which affects the thyroid gland), Guillain-Barré syndrome (which affects the nervous system) or polymyositis (which affects the muscles). Autoimmune disorders may occur many months after the start of treatment.
- **Kidney stones:** There have been reports of kidney stones.
- **Serious skin reactions:** Serious skin reactions including Stevens-Johnson syndrome (SJS), erythema multiforme and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in patients receiving Mylan-Atazanavir.

See the [Serious side effects and what to do about them](#) table below for more information on these and other serious side effects.

Diabetes and high blood sugar: There have been reports of increased blood sugar and development or worsening of diabetes in patients using protease inhibitors like Mylan-Atazanavir. Tell your healthcare professional if you have diabetes or a history of high blood sugar. If you take insulin or oral medicines to control your blood sugar your dose might need to be changed.

Fat redistribution: Changes in body fat have been seen in some patients taking antiretroviral medicine. These changes may include increased amount of fat in the upper back and neck (buffalo hump), the breasts and around the trunk. Loss of fat from the legs, arms and face may also happen.

Pregnancy and breastfeeding:

- Tell your healthcare professional if you are pregnant, think you might be pregnant or are planning to become pregnant. It is not known if Mylan-Atazanavir can harm your unborn baby.
- Pregnant women have experienced serious side effects when taking Mylan-Atazanavir with other HIV medicines called nucleoside analogues.
- If you get pregnant while taking Mylan-Atazanavir you and your healthcare professional will need to decide if Mylan-Atazanavir is right for you.
- There is a registry for women who take antiretroviral medicines during pregnancy called the Antiretroviral Pregnancy Registry. The purpose of this registry is to collect information about the health of you and your baby. If you take Mylan-Atazanavir while you are pregnant, talk to your healthcare professional about taking part in the registry.
- Mylan-Atazanavir passes into breast milk. You should not take Mylan-Atazanavir if you are breastfeeding. This is also to avoid transmission of HIV to your infant through breast milk. Talk to your healthcare professional about how to feed your baby.

Infecting others with HIV: Mylan-Atazanavir will not stop you from passing HIV to others, although this risk is lower if you take your HIV medicine as instructed by your healthcare professional. You should take steps to avoid this by:

- Using condoms when you have oral or penetrative sex.
- Not reusing or sharing needles, syringes, or other injection equipment.

Blood tests and monitoring: Mylan-Atazanavir can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

Do NOT take any of the following drugs with Mylan-Atazanavir:

- medicines to treat HIV infection such as nevirapine (VIRAMUNE*).
- medicines used to thin the blood and prevent blood clots such as apixaban (ELIQUIS®) and rivaroxaban (XARELTO*).
- medicines used to treat schizophrenia and bipolar depression such as lurasidone (LATUDA*).
- medicines used to prevent seizures such as carbamazepine (TEGRETOL*), phenytoin (DILANTIN*), and phenobarbital.
- medicines used to treat certain types of cancer such as apalutamide (ERLEADA*), irinotecan (CAMPTOSAR*), encorafenib (BRAFTOVI*), neratinib (NERLYNX*), and venetoclax (VENCLEXTA*).
- medicines used to treat gout such as colchicine (MYFLINA*).
- medicines used to treat migraines such as dihydroergotamine, ergonovine, ergotamine, methylergonovine, and ergot alkaloid.

- medicines used to treat high cholesterol such as lomitapide (JUXTAPID*), lovastatin (MEVACOR*), and simvastatin (ZOCOR*).
- medicines used to treat the liver disease Hepatitis C such as elbasvir/grazoprevir (ZEPATIER*), and glecaprevir/pibrentasvir (MAVIRET*).
- alfuzosin (XATRAL*), a medicine used to treat benign prostate gland enlargement.
- medicines used to treat irregular heartbeats such as amiodarone (CORDARONE*), dronedarone (MULTAQ*), flecainide (TAMBOCOR*), propafenone (RYTHMOL*), and quinidine (BIQUIN*).
- medicines used to treat chronic angina (chest pain) such as ranolazine (CORZYNA*).
- medicines used to treat motor and verbal tics caused by Tourette's disorder such as pimozide (ORAP*).
- medicines used to reduce the risk of cardiovascular events, ticagrelor (BRILINTA*).
- medicines used to treat bacterial infections (e.g., tuberculosis) such as rifampin (RIFADIN*, RIFATER*, or ROFACT*).
- medicines used for asthma and chronic obstructive pulmonary disease (COPD) such as salmeterol (SEREVENT*).
- sildenafil (REVATIO*), a medicine used to treat the lung disease pulmonary arterial

The following may also interact with Mylan-Atazanavir:

- antipsychotics, medicines used to treat mental health problems (e.g., schizophrenia and bipolar disorder) such as quetiapine (SEROQUEL* or SEROQUEL* XR), and lurasidone (LATUDA*) when used without ritonavir.
- endothelin receptor antagonists, medicines used to treat pulmonary arterial hypertension (high blood pressure in the lungs) such as bosentan (TRACLEER*) when taken with Mylan-Atazanavir without ritonavir.
- proton pump inhibitors, medicines used for indigestion and heart burn or ulcers such as omeprazole (LOSEC*).
- Hepatitis C direct-acting antivirals, medicines used to treat Hepatitis C infections such as sofosbuvir/velpatasvir/voxilaprevir (VOSEVI*).
- inhaled beta agonists, medicines used to treat breathing problems like asthma and COPD such as salmeterol (SEREVENT DISKUS*), and salmeterol with fluticasone (ADVIR*).
- phosphodiesterase type 5 (PDE5) inhibitors for erectile dysfunction such as sildenafil (VIAGARA*), and tadalafil (CIALIS*).
- phosphodiesterase type 5 (PDE5) inhibitors for pulmonary arterial hypertension (high blood pressure in the lungs) such as sildenafil (REVATIO*), and tadalafil (ADCIRCA*).
- antiplatelets, medicines used to prevent blood clots such as clopidogrel (PLAVIX*).
- other antivirals, medicines used to treat HIV and AIDS such as didanosine (VIDEX®) buffered formulations or didanosine EC formulation. ***Mylan-Atazanavir must be taken with a meal either 1 hour before or 2 hours after taking these types of drugs;*** tenofovir disoproxil fumarate (VIREAD*), efavirenz, saquinavir (soft gelatine capsules), ritonavir (NORVIR*), and other protease inhibitors.
- antacids, medicines used to treat heartburn and stomach upset; ***Mylan-Atazanavir must be taken with a meal either 1 hour before or 2 hours after taking these types of drugs.***

- antiarrhythmics, medicines used to treat irregular heartbeat such as lidocaine (when given by injection).
- anticoagulants, medicines used to thin the blood and prevent blood clots such as warfarin (COUMADIN®), dabigatran (PRADAXA*), and edoxaban (LIXIANA*).
- antidepressants, medicines used to treat depression such as tricyclic antidepressants, amitriptyline (ELAVIL*), imipramine (TOFRANIL*), and trazodone (OLEPTRO*).
- anticonvulsants, medicines used to prevent seizures such as lamotrigine (LAMICTAL*).
- antifungals, medicines used to treat fungal infections such as ketoconazole (NIZORAL*), itraconazole (SPORANOX*), and voriconazole (VFEND*).
- antimycobacterials, medicines used to treat infections like tuberculosis (TB) such as rifabutin (MYCOBUTIN*).
- benzodiazepines, medicines often used to treat anxiety such as midazolam when injected.
- gonadotropin-releasing hormone antagonist receptor (GnRH) antagonists, medicines used to suppress sex hormone production such as elagolix (ORILISSA*).
- calcium channel blockers, medicines used to lower blood pressure such as diltiazem (CARDIZEM* or TIAZAC*), desacetil diltiazem, felodipine (PLENDIL*), nifedipine (ADALAT*), nicardipine (CARDENE*), and verapamil (SOPTIN* or VERELAN*).
- kinase inhibitors, medicines used to treat low blood platelets such as fostamatinib (TAVALISSE*).
- hydroxymethylglutaryl-CoA (HMG-CoA) reductase inhibitors, medicines used to lower cholesterol such as atorvastatin (LIPITOR*), and rosuvastatin (CRESTOR*).
- immunosuppressants, medicines used in organ transplants such as cyclosporin (SANDIMMUNE* or NEORAL*), tacrolimus (PROGRAF*), and sirolimus (RAPAMUNE*).
- corticosteroids, medicines used to treat inflammation such as dexamethasone, and fluticasone propionate (FLONASE* or FLOVENT*).
- antibiotics, medicines used to treat bacterial infections such as clarithromycin (BIAXIN*).
- oral contraceptives, medicines used for birth control such as ethinyl estradiol, norgestimate, and norethindrone.
- stomach acid reducing agents such as famotidine (PEPCID AC*).

How to take Mylan-Atazanavir:

- Take Mylan-Atazanavir exactly as your healthcare professional has told you. Do not change your dose or stop taking Mylan-Atazanavir without talking to your healthcare professional.
- Mylan-Atazanavir should always be taken with other antiretrovirals used to treat HIV infection.
- Mylan-Atazanavir should be taken with food at about the same time each day.
- Mylan-Atazanavir capsules should not be opened, they should be swallowed whole with water.

Usual dose:

For adults, who have never taken HIV medicines before:

- 300 mg once daily taken with ritonavir 100 mg once daily;
OR
- 400 mg (two 200 mg capsules) once daily (without ritonavir).

For adults who have taken HIV medicines before:

- 300 mg once daily taken with ritonavir 100 mg once daily.

For children from 6 to 18 years of age, weighing at least 20 kg:

- Your child's healthcare professional will decide on the dose that is best for them depending on their weight.

Overdose:

If you think you, or a person you are caring for, have taken too much Mylan-Atazanavir, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take a dose, take the dose you missed as soon as possible with some food, and then return to your normal schedule. However, if a dose is skipped, do not double the next dose. Continue as normal with your next dose.

What are possible side effects from using Mylan-Atazanavir?

These are not all the possible side effects you may have when taking Mylan-Atazanavir. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- nausea,
- vomiting,
- diarrhea,
- abdominal pain,
- indigestion,
- headache,
- dizziness,
- insomnia,
- fever,
- muscle pain.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Liver problems: high liver blood test results, nausea, vomiting, loss of appetite, swelling, pain, aching		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
or tenderness on the right side below the ribs, yellowing of the skin or eyes (jaundice), dark urine, pale stool, unusual tiredness			
Rash: redness, itching	√		
UNCOMMON			
Lactic acidosis (too much lactic acid in the blood): weight loss, fatigue, malaise, loss of appetite, unusual muscle pain, feeling dizzy or lightheaded, fast or irregular heartbeat, shortness of breath, feeling unusually cold, especially in arms and legs, severe hepatomegaly (swollen and enlarged liver) with symptoms of liver problems such as nausea, vomiting, stomach pain, weakness, diarrhea		√	
RARE			
Allergic reaction: difficulty swallowing or breathing, wheezing, drop in blood pressure, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat			√
Angioedema (swelling of tissue under the skin): difficulty breathing, swelling of face, tongue, throat, hands and feet, genitals and digestive tract causing diarrhea, nausea and vomiting			√
Diabetes and high blood sugar: excessive thirst, urination and hunger, unexplained weight loss, poor wound healing, infections		√	
Gallbladder problems (gallstones and inflammation): fever, nausea, pain that radiates to your shoulder or back, severe pain in your upper right abdomen, vomiting, yellowing of the skin or eyes (jaundice), pale stool, dark urine		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Heart problems: irregular heartbeat, dizziness, lightheadedness, shortness of breath		√	
Immune reconstitution inflammatory syndrome and autoimmune disorders: fever, redness, rash or swelling, fatigue, joint or muscle pain, numbness or weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, chest pain or rapid heart rate, yellowing of the eyes and skin, anxiety and irritability accompanied by tremor of your hands or fingers, muscle weakness in your hips, thighs, shoulders, upper arms and neck		√	
Kidney stones: pain in your side, blood in your urine, pain when you urinate			√
Severe skin reactions (erythema multiforme, SJS, DRESS): severe rash, itching, fever, swollen lymph glands, flu-like feeling, blisters and peeling of skin that may start in and around the mouth, nose, eyes and genitals and spread to other areas of the body, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feeling thirsty, urinating less often, less urine			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/healthcanada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep out of the reach and sight of children.

Store Mylan-Atazanavir at controlled room temperature (15°C to 30°C). Protect from moisture.

If you want more information about Mylan-Atazanavir:

- Talk to your healthcare professional.
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.mylan.ca, or by calling 1-844-596-9526.

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