

## 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, Drugs that must NOT be taken with Mylan-Atazanavir](#)
- you are allergic to atazanavir or any of the non-medicinal ingredients in Mylan-Atazanavir (See [What are the 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 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
  - 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:

- **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.
- **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.
- **Gallbladder problems:** Gallstones and gallbladder inflammation have been reported.
- **Kidney stones:** There have been reports of kidney stones.

See the [Serious side effects and what to do about them](#) table 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.**

**The following may interact with Mylan-Atazanavir:**

### Serious Drug Interactions

**Drugs that must NOT be taken with Mylan-Atazanavir:**

- if you are also taking ritonavir (NORVIR\*) to treat your HIV infection:
  - apixaban (ELIQUIS®) and rivaroxaban (XARELTO\*), oral anticoagulants, used to thin the blood and prevent blood clots
  - lurasidone (LATUDA\*), used to treat schizophrenia and bipolar depression
- indinavir (CRIXIVAN\*) and nevirapine (VIRAMUNE\*), other medicines to treat your HIV infection
- apalutamide (ERLEADA\*) and irinotecan (CAMPTOSAR\*), medicines used to treat cancer
- dihydroergotamine, ergonovine, ergotamine, methylergonovine, ergot alkaloid medicines used to treat migraines
- lomitapide (JUXTAPID\*), lovastatin (MEVACOR\*), simvastatin (ZOCOR\*), medicines used to treat high cholesterol
- elbasvir/grazoprevir (ZEPATIER\*), glecaprevir/pibrentasvir (MARIVET\*), medicines used to treat the liver disease Hepatitis C
- alfuzosin (XATRAL\*), used to treat benign prostate gland enlargement
- pimozide (ORAP\*), used to treat motor and verbal tics caused by Tourette’s disorder
- quinidine (BIQUIN\*), used to treat irregular heartbeat
- ticagrelor (BRILINTA\*), used to reduce the risk of cardiovascular events
- rifampin (RIFADIN\*, RIFATER\*, or ROFACT\*), used to treat bacterial infections such as tuberculosis • sildenafil (REVATIO\*), used to treat the lung disease pulmonary arterial hypertension (PAH)
- St. John’s wort (*Hypericum perforatum*), an herbal product used to treat depression
- triazolam (HALCION\*), used to treat insomnia
- vardenafil (LEVITRA\*), used for erectile dysfunction

**Drugs that are not recommended to be taken with Mylan-Atazanavir:**

Type of Drug	Examples of Generic Names (Brand Names)
Antipsychotics, used to treat schizophrenia and bipolar disorder	quetiapine (SEROQUEL*, SEROQUEL* XR)
Endothelin receptor antagonist, used to treat pulmonary arterial hypertension (high blood pressure in the lungs)	bosentan (TRACLEER*), when taken with Mylan-Atazanavir without ritonavir
Proton pump inhibitors, used for indigestion and heart burn or ulcers	omeprazole (LOSEC*)
Hepatitis C direct-acting antivirals, used to treat Hep C infections	sofosbuvir/velpatasvir/voxilaprevir (VOSEVI*)

Inhaled beta agonists, used to treat breathing problems like asthma and COPD	salmeterol (SEREVENT DISKUS*), salmeterol with fluticasone (ADVIR*)
PDE5 inhibitors, for erectile dysfunction	ildenafil (LEVITRA*), sildenafil (VIAGARA*), tadalafil (CIALIS*)
PDE5 inhibitors, for pulmonary arterial hypertension (high blood pressure in the lungs)	tadalafil (ADCIRCA*)
Antiplatelets, used to prevent blood clots	clopidogrel (PLAVIX*)

**Drugs that interact with Mylan-Atazanavir where the dose of Mylan-Atazanavir or the dose of the other drug should be changed or where more instructions from your healthcare professional are needed:**

Type of Drug	Examples of Generic Names (Brand Names)
Other antiviral medicines used to treat HIV and AIDS	<p>didanosine (VIDEX®) buffered formulations or didanosine EC formulation</p> <p><b>Mylan-Atazanavir must be taken with a meal either 1 hour before or 2 hours after taking these types of drugs.</b></p> <p>tenofovir DF (VIREAD*), efavirenz, nevirapine, boceprevir, saquinavir (soft gelatin capsules), ritonavir (NORVIR*), other protease inhibitors</p>
Antacids, used to treat heartburn and stomach upset	<b>Mylan-Atazanavir must be taken with a meal either 1 hour before or 2 hours after taking these types of drugs.</b>
Antiarrhythmics, used to treat irregular heartbeat	amiodarone (CORDARONE*), lidocaine (when given by injection)
Anticoagulants, used to thin the blood and prevent blood clots	warfarin (COUMADIN®), dabigatran (PRADAXA*), edoxaban (LIXIANA*), rivaroxaban (XARELTO*), apixaban (ELIQUIS*)
Antidepressants, used to treat depression	tricyclic antidepressants, amitriptyline (ELAVIL*), desipramine, imipramine (TOFRANIL*), trazodone (OLEPTRO*)

Antiepileptics, used to prevent seizures	carbamazepine (TEGRETOL*), phenytoin (DILANTIN*), phenobarbital, lamotrigine (LAMICTAL*)
Antifungals, used to treat fungal infections	ketoconazole (NIZORAL*), itraconazole (SPORANOX*), voriconazole (VFEND*)
Antigout, used to treat gout	colchicine
Antineoplastics, used to treat cancer	encorafenib (BRAFTOVI*)
Antimycobacterials, used to treat infections like tuberculosis (TB)	rifabutin (MYCOBUTIN*)
Antipsychotics, used to treat mental health problems	lurasidone (LATUDA*), when used without ritonavir
Benzodiazepines, sedatives often used to treat anxiety	midazolam, when injected
Gonadotropin-releasing hormone antagonist Receptor (GnRH) Antagonists, used to suppress sex hormone production	elagolix (ORILISSA*)
Calcium channel blockers, used to lower blood pressure	diltiazem (CARDIZEM* or TIAZAC*), desacetyldiltiazem, felodipine (PLENDIL*), nifedipine (ADALAT*), nicardipine (CARDENE*), verapamil (SOPTIN*, VERELAN*)
Kinase inhibitors, used to treat low blood platelets	fostamatinib (TAVALISSE*)
HMG-CoA Reductase Inhibitors, used to lower cholesterol	atorvastatin (LIPITOR*), rosuvastatin (CRESTOR*)
Immunosuppressants, used in organ transplants	cyclosporin (SANDIMMUNE*, NEORAL*), tacrolimus (PROGRAF*), sirolimus (RAPAMUNE*)
Corticosteroids, used to treat inflammation	dexamethasone, fluticasone propionate (FLONASE*, FLOVENT*)

Antibiotics, used to treat bacterial infections	clarithromycin (BIAXIN*)
Oral contraceptives, used for birth control	ethinyl estradiol, norgestimate or norethindrone
Stomach acid reducing agents	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	
<b>COMMON</b>			
<b>Rash:</b> redness, itching	√		
<b>Liver problems:</b> high liver blood test results, nausea, vomiting, loss of appetite, swelling, pain, aching or tenderness on the right side below the ribs, yellowing of the skin or eyes (jaundice), dark urine, pale stool, unusual tiredness		√	
<b>UNCOMMON</b>			
<b>Lactic acidosis</b> (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		√	
<b>RARE</b>			
<b>Diabetes and high blood sugar:</b> excessive thirst, urination and hunger, unexplained weight loss, poor wound healing, infections		√	



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	
<b>Heart problems:</b> irregular heartbeat, dizziness, lightheadedness, shortness of breath		√	
<b>Gallbladder problems</b> (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		√	
<b>Kidney stones:</b> pain in your side, blood in your urine, pain when you urinate			√
<b>Angioedema</b> (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			√
<b>Immune reconstitution inflammatory syndrome and Autoimmune disorders:</b> 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		√	
<b>Severe skin reactions</b> (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			√

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	
eyes, shortness of breath, dry cough, chest pain or discomfort, feeling thirsty, urinating less often, less urine			
<b>Allergic reaction:</b> 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			√

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/health-canada/services/drugs-health-products/medeffect-canada.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 health 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](http://www.mylan.ca), or by calling 1-844-596-9526.

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