

ATAZANAVIR MYLAN

Atazanavir (as sulfate) Capsules 150 mg, 200 mg & 300 mg



What is in this leaflet

Please read this leaflet carefully before you start taking Atazanavir Mylan.

This leaflet answers some common questions about Atazanavir Mylan.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Atazanavir Mylan against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Atazanavir Mylan is used for

Atazanavir Mylan is used in combination with other anti-HIV agents to treat adults and children aged between 6 and 18 years of age who are infected with Human Immunodeficiency Virus (HIV).

This medicine belongs to a group of medicines called protease inhibitors.

Atazanavir Mylan contains the active ingredient atazanavir sulfate. It belongs to a group of medicines called protease inhibitors.

What is HIV

HIV is a virus that kills important cells in the immune system over time (e.g. CD4 cells). When HIV has killed enough of the immune cells, your body becomes prone to certain

types of infections. Some infections are the cause of "AIDS-defining" illnesses. This is when someone is said to have developed Acquired Immunodeficiency Syndrome or AIDS. AIDS is a serious condition and can lead to death.

How Atazanavir Mylan works

When HIV infects cells in the immune system, it takes over part of the cell's internal workings and uses the contents of the cell to produce new viruses.

Atazanavir Mylan helps to block HIV protease, an enzyme that is needed for the HIV virus to multiply.

Atazanavir Mylan may lower the amount of HIV in your blood and help your body keep its supply of CD4 and T-cells. Interfering with the production of new viruses helps to reduce the total amount of HIV in the body and slows down the damage to the immune system.

Atazanavir Mylan is not a cure for HIV infection. Taking it will not necessarily prevent the illnesses that commonly occur in people with HIV infection or AIDS. You can still infect other people with HIV while you are taking this medicine.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

This medicine is not addictive

Before you take Atazanavir Mylan

When you must not take it

Do not take Atazanavir Mylan if you have an allergy to:

- any medicine containing atazanavir
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine if you have severe liver disease.

Do not take this medicine if you are currently taking any of these medicines:

- rifampicin – a medicine used to treat tuberculosis
- medicines used to treat psychotic problems containing pimozone or lurasidone
- cholesterol reducing medicines such as lovastatin, simvastatin or lomitapide
- cisapride – a medicine used to treat gastric reflux
- sleeping tablets containing midazolam or triazolam
- medicines to treat migraine or severe headaches which contain ergotamine
- herbal products which contain St John's wort (*Hypericum perforatum*)
- alfuzosin – a medicine used in bladder disorders
- asthma medications salmeterol
- medicines used to treat hepatitis C containing elbasvir/grazoprevir or glecaprevir/pibrentasvir

- sildenafil – if you are taking it for pulmonary arterial hypertension

If you are taking Atazanavir Mylan with another medicine for the treatment of HIV called ritonavir, then you should not take certain medicines such as calcium channel blockers including bepridil or a medication known as quinidine. You should also inform your doctor if you are taking fluticasone propionate.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- liver problems including hepatitis, yellowing of the skin or eyes (jaundice) or prior use of medicines toxic to the liver. Liver problems may cause higher levels of Atazanavir Mylan in the blood, increasing the chance of side effects
- kidney problems or high risk for chronic kidney disease
- haemophilia; haemophilia patients may experience increased bleeding when taking Atazanavir Mylan
- any problems with irregular heart beat
- diabetes or impaired glucose tolerance.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breast feeding or plan to breast-feed.

Atazanavir passes into breast milk. Therefore, to avoid possible side effects in the nursing infant, mothers should stop breast-feeding if they are taking Atazanavir Mylan.

If you have not told your doctor about any of the above, tell them before you start taking Atazanavir Mylan.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking Atazanavir Mylan.

Medicines for HIV

Atazanavir Mylan will be given with other anti-HIV medicines may affect the way Atazanavir Mylan works, and Atazanavir Mylan may affect the way some other anti-HIV medicines work.

Your doctor has all the current information on the effects these medicines have on one another and will discuss with you the combination of medicines that you should be taking.

Medicines for other conditions

Some medicines may interfere with Atazanavir Mylan. These include:

- medicines to treat hepatitis (e.g. telaprevir, boceprevir, sofosbuvir/velpatasvir/voxilaprevir)
- medicines used to treat stomach ulcers or other stomach disorders such as proton-pump inhibitors (such as omeprazole) or histamine-2 receptor antagonists (such as cimetidine, famotidine or ranitidine)
- antacids or buffered medicines reduce the absorption of atazanavir. These medicines should be taken one hour before or two hours after Atazanavir Mylan

- medicines that affect the electrical activity of the heart such as amiodarone, lidocaine, quinidine
- anticoagulant medicines such as warfarin, dabigatran, rivaroxaban, apixaban
- medicines to manage depression (tricyclic antidepressants)
- anticonvulsant medications (carbamazepine, phenytoin, phenobarbitone or lamotrigine) used to treat epilepsy
- antifungal medication (voriconazole) used to treat fungal infections
- calcium channel blockers (such as diltizem, felodipine, nifedipine, nicardipine or verapamil) used to treat high blood pressure
- erectile dysfunction agents such as sildenafil, tadalafil and vardenafil
- cholesterol lowering medication (atorvastatin)
- macrolide antibiotics (clarithromycin, roxithromycin, erythromycin or azithromycin) used to treat various infections
- oral contraceptives or the patch
- pain medications (buprenorphine)
- gout medications (colchicine)
- bosentan, a medication used to treat pulmonary arterial hypertension.

These medicines may be affected by Atazanavir Mylan or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Atazanavir Mylan

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle/package, ask your doctor or pharmacist for help.

How much to take

If you are new to HIV treatment, your doctor may prescribe Atazanavir Mylan 400 mg (2 x 200 mg capsules) once a day with food,

Or

Atazanavir Mylan 300 mg once daily (two 150 mg capsules) with ritonavir (100 mg daily) taken with food.

If you have been on previous HIV treatment, the usual dose is Atazanavir Mylan 300 mg once daily (two 150 mg capsules) with ritonavir (100 mg daily) taken with food.

You doctor will tell you what dose of Atazanavir Mylan you should take.

If you are between the ages of 6 and 18 years, the dose will be different. Please follow your doctor's instructions.

How to take it

Swallow the capsules whole with a full glass of water.

Atazanavir Mylan should be taken with food.

When to take it

Take your medicine at about the same time each day. taking it at the same time each day will have the best effect. It will also help you remember when to take it.

If you need to take an antacid, take it at least 2 hours before or 2 hours after your dose of Atazanavir Mylan.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your

condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

It is very important not to miss a dose of your medicine. If you miss doses the virus may become resistant to your HIV medicines.

While you are taking Atazanavir Mylan

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Atazanavir Mylan.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

You may wish to discuss disclosure issues with your doctor about who should know that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

You should have your liver function and blood tested on a regular basis when your doctor advises you to ensure that your body chemistry is functioning normally and that your medicine is working.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take Atazanavir Mylan to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Atazanavir Mylan affects you.

This medicine may cause dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Atazanavir Mylan. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Atazanavir Mylan.

This medicine helps most people with HIV infection, but it may have

unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea or vomiting
- diarrhoea
- dyspepsia (upset stomach)
- flatulence (wind)
- headache
- fatigue
- dizziness
- insomnia
- loss of strength and energy

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- tingling of the hands or feet
- abdominal pain, abdominal distension or tenderness
- changes to the distribution of fat on your body
- pain in the joints or muscle pain
- ulcers in the mouth, oesophagus (pain or burning on swallowing) or stomach (pain or indigestion)
- rash
- change in heart rhythm
- fainting
- signs or symptoms of kidney stones (pain in your side, blood in your urine, pain when you urinate)
- signs of symptoms of gallstones or gallbladder inflammation (pain in the

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or

go to Accident and Emergency at your nearest hospital:

- liver problems including yellowing of the skin or eyes, also called jaundice; this may occur with vomiting, fever and dark coloured urine
- lactic acidosis – symptoms include nausea, vomiting, unusual or unexpected stomach discomfort, feeling very weak and tired, shortness of breath, or weakness in the arms and legs.
- allergic reaction – swelling of the face, lips, or throat which makes breathing difficult.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking Atazanavir Mylan

Storage

Keep your capsules in the bottle/pack until it is time to take them.

If you take the capsules out of the bottle/pack they may not keep well.

Keep your capsules in a cool dry place where the temperature stays below 25°C.

Do not store Atazanavir Mylan or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Atazanavir Mylan 150 mg capsule: greenish-blue opaque cap and blue opaque body, hard-shell gelatin capsule filled with white to pale yellow powder. The capsule is axially printed with MYLAN over AR150 in black ink on both the cap and body.

Atazanavir Mylan 200 mg capsule: blue opaque cap and greenish-blue opaque body, hard-shell gelatin capsule filled with white to pale yellow powder. The capsule is axially printed with MYLAN over AR200 in black ink on both the cap and body.

Ingredients

Active ingredient:

Atazanavir Mylan contains 150 mg or 200 mg of atazanavir as the active ingredient.

Inactive ingredients:

Atazanavir Mylan also contains:

- lactose
- crospovidone
- magnesium stearate

The capsule shell contains

- gelatin
- titanium dioxide
- iron oxide red (150 mg)
- iron oxide yellow (200 mg)
- indigo carmine (200 mg)
- patent blue V
- black printing ink

Contains sugars as lactose.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Atazanavir Mylan is supplied in New Zealand by:

Viatris Ltd
PO Box 11-183
Ellerslie
AUCKLAND
www.viatris.co.nz
Telephone 0800 168 169

Date of Preparation

11 November 2022
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