

ATAZANAVIR MYLAN

atazanavir (as sulfate)

Consumer Medicine Information

What is in this leaflet

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 belongs to a group of medicines called protease inhibitors.

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).

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.

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

ATAZANAVIR MYLAN is not addictive.

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

Before you take ATAZANAVIR MYLAN

It is important that you check the information below 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 ATAZANAVIR MYLAN if you have severe liver disease.

Do not take ATAZANAVIR MYLAN if you are currently taking any of these medicines:

- rifampicin - a medicine used to treat tuberculosis
- sildenafil - if you are taking it for pulmonary arterial hypertension
- irinotecan - a medicine used to treat some cancers
- cisapride - a medicine used to treat gastric reflux
- alfuzosin - a medicine used in bladder disorders
- asthma medications salmeterol (Seretide, Serevent)
- cholesterol reducing medicines (lovastatin, simvastatin)
- sleeping tablets containing midazolam or triazolam
- medicines used to treat psychotic problems containing pimozone or lurasidone
- medicines to treat migraine or severe headaches which contain ergotamine
- herbal products which contain St John's wort (*Hypericum perforatum*)
- protease inhibitor - indinavir (Crixivan)
- medicines used to treat hepatitis C containing elbasvir/grazoprevir or glecaprevir/pibrentasvir

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.

If you are not sure if any of these medicines are in the products you are taking, talk to your doctor or pharmacist.

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.

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 are pregnant or intend to become pregnant.

Experience is limited with the use of ATAZANAVIR MYLAN in pregnant women. Therefore, it should not be used during pregnancy unless it is clearly needed. If there is an urgent need to consider ATAZANAVIR MYLAN during pregnancy, your doctor will discuss with you the benefits and risks of taking it.

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

It is not known whether ATAZANAVIR MYLAN 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 (breast-feeding can also transfer HIV to babies)

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
- have any of the following risk factors for chronic kidney disease:
 - diabetes
 - high blood pressure
 - established heart problems (heart failure or heart attack) or have had a stroke
 - a family history of kidney failure
 - are obese with a body mass index (BMI) 30 or higher
 - are a smoker
 - are 60 years of age or older
 - are of Aboriginal or Torres Strait Islander origin
 - have a history of acute kidney injury
- haemophilia; haemophiliac patients may experience increased bleeding when taking ATAZANAVIR MYLAN any problems with irregular heart beat
- diabetes or impaired glucose tolerance

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

Taking other medicines

ATAZANAVIR MYLAN has the potential to adversely interact with many other drugs.

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

Medicines for HIV

ATAZANAVIR MYLAN will be given with other anti-HIV medicines; some of these 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

You should tell your doctor if you are taking any of the following medicines:

- medicines to treat hepatitis (e.g. telaprevir, boceprevir, sofosbuvir/velpatasvir/ voxilaprevir)
- proton-pump inhibitors or histamine-2 receptor antagonists (medicines used to treat stomach ulcers or other stomach disorders). If you plan to take or are currently taking either histamine-2 receptor antagonists (such as cimetidine, famotidine, ranitidine or other medicines in this class) or proton-pump inhibitors (such as omeprazole or others in this class of medicine), then you must speak to your doctor as these may reduce the effectiveness of ATAZANAVIR MYLAN. Depending on your medical history these medicines may not be suitable for you. Talk to your doctor for further information
- macrolide antibiotics (clarithromycin, roxithromycin, erythromycin or azithromycin) used to treat various infections
- antifungal medication (voriconazole) used to treat fungal infections
- anticonvulsant medications (carbamazepine, phenytoin, phenobarbital or lamotrigine) used to treat epilepsy
- erectile dysfunction agents used to treat impotence - sildenafil (Viagra), tadalafil (Cialis), vardenafil (Levitra)
- amiodarone, bepridil, lignocaine, quinidine or tricyclic antidepressants - if you take any of these medicines, your doctor may ask you to have blood tests just to make sure that ATAZANAVIR MYLAN and the other medicine are not affecting the way each medicine works
- calcium channel blockers (such as diltiazem, felodipine, nifedipine, nicardipine or verapamil) - medicines used to treat high blood pressure
- antacids and buffered medicines reduce the absorption of ATAZANAVIR MYLAN. These medicines should be taken one hour before or two hours after ATAZANAVIR MYLAN.
- drugs that affect the electrical activity of the heart
- oral contraceptives - ATAZANAVIR MYLAN may affect the safety and effectiveness of birth control pills or the patch. Speak to your doctor about the type of contraception that is most suitable for you
- pain medications (buprenorphine)
- gout medications (colchicine)
- bosentan (Tracleer), a medication used to treat pulmonary arterial hypertension

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

How to take ATAZANAVIR MYLAN

ATAZANAVIR MYLAN should be given only when prescribed by your doctor.

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, 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 (either as one 300 mg capsule or 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 (either as one 300 mg capsule or two 150 mg capsules) with ritonavir (100 mg daily) taken with food.

Your 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 of ATAZANAVIR MYLAN will be different. Please follow your doctor's instructions.

How to take it

Swallow the capsules whole with a drink such as a glass of water or fruit juice.

The dose of ATAZANAVIR MYLAN should be taken with food.

When to take it

You may take ATAZANAVIR MYLAN capsules at any time. It is recommended, however, that you 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.

Talk to your doctor or pharmacist to work out when it is best for you to take your doses 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.

Do not stop taking this medicine unless your doctor tells you to - even if you feel better.

If you forget to take it

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

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 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 when to take your medicine, ask your pharmacist for some hints and inform your doctor that you have missed a dose.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if 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.

While you are taking ATAZANAVIR MYLAN

Things you must do

If you are about to be started on any new medicine, remind your doctor or 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.

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.

Pregnant women have experienced serious side effects when taking this medicine in combination with didanosine (Videx) and stavudine (Zerit).

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 ATAZANAVIR MYLAN 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 without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how ATAZANAVIR MYLAN affects you.

Some patients taking ATAZANAVIR MYLAN have experienced dizziness. It is not known if this was caused by ATAZANAVIR MYLAN. Make sure you know how you react to ATAZANAVIR MYLAN before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy.

Things that may help your condition

Things that may help your general health are suggested below:

- exercise
- healthy eating
- stress reduction
- counselling
- regular visits to your doctor to monitor your health
- good oral hygiene
- support groups

Talk with your doctor about all of the above suggestions. You can also access further information about HIV and services for people with HIV by contacting your local

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

Do not be alarmed by the following list of side effects. You may not experience any of them.

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

Your doctor may monitor your kidney function prior to, and during, your treatment with ATAZANAVIR MYLAN.

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

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

These are some of the more common side effects of ATAZANAVIR MYLAN.

Tell your doctor or pharmacist immediately if you notice any of the following:

- tingling of the hands or feet
- abdominal pain, abdominal distension or tenderness, vomiting
- changes to the distribution of fat on your body
- pain in the joints, muscle pain
- ulcers in the mouth, oesophagus (pain or burning on swallowing) or stomach (pain or indigestion)
- rash
- change in heart rhythm, fainting

These are serious side effects. You may need urgent medical attention or hospitalisation.

Yellowing of the skin or eyes

One of the other side effects that can occur with ATAZANAVIR MYLAN is yellowing of the skin (jaundice) or eyes (scleral icterus). Yellowing of the skin or eyes is caused by an increase in a substance called bilirubin. Bilirubin is formed naturally by the breakdown of red blood cells and is usually excreted by the liver.

Call your doctor if your skin or the whites of your eyes turn yellow. Although it is unlikely that these effects will cause damage to your skin, eyes or liver, it is important that you tell your doctor promptly if they occur.

Gallbladder disorders (which may include gallstones and gallbladder inflammation)

If you develop any signs or symptoms of gallstones (pain in the right or middle upper stomach, fever, nausea or vomiting, or yellowing of skin and whites of eyes), tell your doctor promptly.

Kidney stones

If you develop signs or symptoms of kidney stones (pain in your side, blood in your urine, pain when you urinate) tell your doctor promptly.

If any of the following happen, tell your doctor immediately, or go to the Accident and Emergency Centre 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

These are very serious side effects. You may need urgent medical attention or hospitalisation.

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

Other side effects not listed above may also occur in some people.

After taking ATAZANAVIR MYLAN

Storage

Store your capsules in the bottle until it is time to take them.

If you take the capsules out of the bottle 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 that is left over.

Product description

What it looks like

ATAZANAVIR MYLAN 200 mg capsules - have a blue opaque cap and greenish-blue opaque body filled with a white to pale yellow powder. The capsule is axially printed with MYLAN over AR200 in black ink on both the cap and body.

ATAZANAVIR MYLAN 300 mg capsules - have a red opaque cap and greenish-blue opaque body, filled with a white to pale yellow powder. The capsule is axially printed with MYLAN over AR300 in black ink on both the cap and body.

Ingredients

ATAZANAVIR MYLAN capsules contain either 200 mg or 300 mg of atazanavir (as sulfate) as the active ingredient.

They also contain the following inactive ingredients:

- lactose monohydrate
- crospovidone
- magnesium stearate
- gelatin
- titanium dioxide

- iron oxide yellow (E172)
- iron oxide red (E172)
- brilliant blue (E133)
- erythrosine (E127)
- TekPrint SW-9008 black ink

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

ATAZANAVIR MYLAN is supplied in Australia by:

Alphapharm Pty Limited
(ABN 93 002 359 739)

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
Phone: (02) 9298 3999
www.mylan.com.au

Australian registration numbers:

ATAZANAVIR MYLAN 200 mg: AUST R 255296

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This leaflet was prepared in February 2019.

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