

EVOTAZ® Tablets

(Ev-oh-taz)

Atazanavir (Ata-zan-a-vir) and Cobicistat (Co-bi-ci-stat)

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking EVOTAZ. This leaflet answers some common questions about EVOTAZ.

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 EVOTAZ 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 EVOTAZ is used for

EVOTAZ contains two active ingredients, atazanavir and cobicistat. Atazanavir belongs to a group of medicines called protease inhibitors. Cobicistat is a type of medicine called a pharmacokinetic enhancer (or "booster"). Cobicistat is included to improve the effect of atazanavir by increasing the level of atazanavir in your body.

EVOTAZ is for adults. EVOTAZ is used in combination with other anti-HIV agents to treat adults 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 the Acquired Immunodeficiency Syndrome or AIDS. AIDS is a serious condition and can lead to death.

How EVOTAZ Works

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

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

EVOTAZ 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 EVOTAZ has been prescribed for you.

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

Before you take EVOTAZ

It is important that you check the information below before you take EVOTAZ.

When you must not take EVOTAZ

Do not take EVOTAZ if you have an allergy to it or to any other ingredients in the formulation listed at the end of this leaflet.

Do not take EVOTAZ if you have liver disease.

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

- Other HIV medication including other protease inhibitors (eg. saquinavir, indinavir, elvitegravir, nevirapine, efavirenz, ritonavir)
- Antimycobacterial medication used to treat conditions such as tuberculosis and leprosy (rifampin, rifabutin, rifapentine)
- Sildenafil or tadalafil - if you are taking for pulmonary arterial hypertension
- Cisapride - a medicine used to treat gastric reflux
- Alfuzosin - a medicine used in bladder disorders
- Asthma medication containing salmeterol (Seretide, Serevent)
- Cholesterol reducing medicines (lovastatin, simvastatin, lomitapide)
- Sleeping tablets containing midazolam or triazolam
- Medicines to treat psychotic problems containing pimozide or lurasidone
- Antiarrhythmics (eg. dronedarone, quinidine)
- Calcium channel blockers (eg. bepridil)
- Medicines to treat migraine or severe headaches which contain ergot derivatives (dihydroergotamine, ergonovine, ergotamine, methylethergonovine)
- Herbal products which contain St John's wort (*Hypericum perforatum*)
- Irinotecan - a medicine used to treat cancer
- Medicines to treat hepatitis C containing elbasvir/grazoprevir or glecaprevir/pibrentasvir

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 use EVOTAZ after the expiry date printed on the back of the pack. If this medicine is taken after the expiry date has passed, it may not work as well.

Do not take EVOTAZ if the packaging is torn or shows signs of tampering.

Before you start to take EVOTAZ

Tell your doctor if you:

1. are taking any other HIV medication
2. have allergies to:
 - any other medicines you have been given or purchased
 - substances such as foods, preservatives or dyes.

Symptoms of an allergic reaction may include:

swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing, or severe and sudden onset of pinkish, itchy swellings on the skin, also called hives;

3. are pregnant or intend to become pregnant. EVOTAZ is not recommended for use during pregnancy.
4. are breast feeding or planning to breast-feed. You should not breast-feed if you are HIV positive because of the chance of passing the HIV virus to your baby. Also, it is not known if EVOTAZ can pass into your breast milk and if it can harm your baby. Talk with your doctor about the best way to feed your baby.
5. currently experience or have experienced any medical conditions especially:
 - kidney problems or are undergoing kidney dialysis treatment
 - 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 or older
 - are of Aboriginal or Torres Strait Islander origin
 - have a history of acute kidney injury
 - 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 EVOTAZ in the blood, increasing the chance of side effects
 - haemophilia, haemophilic patients may experience increased bleeding when taking EVOTAZ
 - 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 use EVOTAZ.

Taking other medicines

EVOTAZ has the potential to adversely interact with many other drugs.

Be sure to inform your doctor of all medications you are taking including prescribed drugs, over the counter products, natural therapies, vitamin supplements and recreational drugs.

Medicines for HIV:

EVOTAZ may be given with other anti-HIV medicines. Some of these anti-HIV medicines may affect the way EVOTAZ works, and EVOTAZ 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 also tell your doctor if you are taking any of the following medicines:

- Medicines that may affect your kidneys unless you have discussed this with your doctor
- Other medicines to treat HIV (eg. ritonavir, didanosine, tenofovir)

- disoproxil fumarate, efavirenz, nevirapine, etravirine, rilpivirine, maraviroc, saquinavir, indinavir, other protease inhibitors)
- Medicines to treat hepatitis (eg. telaprevir, boceprevir, sofosbuvir/velpatasvir/voxilaprevir)
- Analeptics (eg. modafinil)
- Medicines used to treat cancer (eg. dasatinib, nilotinib, vinblastine, vincristine)
- Anticoagulants (eg. warfarin, dabigatran, apixaban, dabigatran, betrixaban, edoxaban)
- Antineoplastic medication (irinotecan)
- Beta blockers (eg. metoprolol, carvedilol, timolol)
- 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 famotidine or others 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 EVOTAZ. Depending on your medical history these medicines may not be suitable for you. Talk to your doctor for further information.
- Macrolide or ketolide antibiotics (eg. clarithromycin, erythromycin) used to treat various infections
- Medicines to lower cholesterol (eg. atorvastatin, rosuvastatin, pravastatin, fluvastatin)
- Antifungal medication (eg. ketoconazole, voriconazole) used to treat fungal infections
- Anticonvulsant medications (eg. carbamazepine, phenytoin, phenobarbital, clonazepam, ethosuximide) used to treat epilepsy
- Erectile dysfunction agents used to treat impotence (eg. sildenafil, tadalafil, vardenafil).
- 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 EVOTAZ 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 EVOTAZ. These medicines should be taken one hour before or two hours after EVOTAZ.
- Drugs that affect the electrical activity of the heart
- Oral contraceptives - EVOTAZ 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.
- Corticosteroids
- Neuroleptics (eg. perphenazine, risperidone, thioridazine)

- Pain medications (eg. buprenorphine, naloxone, methadone, fentanyl, tramadol)
- Gout medications (colchicine)
- Sedatives (eg. midazolam, triazolam, buspirone, diazepam)
- Bosentan, a medication used to treat pulmonary arterial hypertension.

This is not a complete list of medicines you should tell your doctor about. It is important that you tell your doctor or pharmacist about the medicines you are taking, even if they are not listed in this leaflet. They will be able to provide you with more information than is contained within this leaflet on the medicines you need to be careful with, or should avoid while taking EVOTAZ.

Your doctor will be able to advise you about the most appropriate medications to treat your condition.

How to take EVOTAZ

EVOTAZ 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.

How much to take

Take EVOTAZ exactly as your doctor tells you to take it. Do not change your dose unless your doctor tells you to. Do not stop taking EVOTAZ without first talking to your doctor.

How to take it

Swallow the tablet whole with a drink such as a glass of water or fruit juice. The dose of EVOTAZ should be taken with food. Taking EVOTAZ with food is important to get the right medicine levels in your body.

When to take EVOTAZ

You may take EVOTAZ tablets at any time. It is recommended, however, that you take your medicine at about the same time each day. Taking EVOTAZ at the same time each day will have the best effect. It will also help you remember when to take the tablets.

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

How long to take it

EVOTAZ helps control your condition but does not cure it. Therefore you must take EVOTAZ every day as directed by your doctor. Continue taking EVOTAZ for as long as your doctor tells you to.

Do not stop taking EVOTAZ 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 it 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 EVOTAZ. If you miss doses the virus may become resistant to your HIV medicines.

If you take too much (overdose)

Immediately call your doctor or the Poisons Information Centre on 131126 in Australia, or go to the Accident and Emergency Centre at your nearest hospital if you or anyone else takes too much EVOTAZ.

Do this even if there are no signs of discomfort or poisoning. This may need urgent medical attention.

While you are using EVOTAZ

Things you must do

- If you become pregnant while taking EVOTAZ, tell your doctor immediately.
- If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking EVOTAZ. EVOTAZ may interfere with the medicine you are taking.
- If you are about to have any medical tests, tell your doctor that you are taking EVOTAZ. EVOTAZ may interfere with the results of these tests.
- If you plan to have surgery, tell your doctor or dentist that you are taking EVOTAZ. You may wish to discuss disclosure issues with your doctor about who should know you are taking EVOTAZ.
- You should have your liver functions and blood tested when your doctor advises on a regular basis to ensure that your body chemistry is functioning normally and that EVOTAZ is working.

Things you must not do

- Do not give EVOTAZ to anyone else, even if they have the same condition as you.
- Do not use EVOTAZ to treat any other complaints unless your doctor tells you to.
- Do not stop taking EVOTAZ without checking with your doctor.
- Avoid doing things that can spread HIV infection since EVOTAZ does not stop you from passing the HIV infection to others.

Things to be careful of

- Be careful driving or operating machinery until you know how EVOTAZ affects you. Make sure you know how you react to EVOTAZ before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy.
- Make sure that you visit your doctor regularly throughout your entire course of treatment with EVOTAZ.

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 AIDS Council, Positive Living Centre or PLWHA organisation.

Side effects

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

Your doctor may monitor your kidney function prior to, and during your treatment with EVOTAZ. Your doctor may switch you to an alternative treatment if your kidney function changes.

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

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 EVOTAZ.

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 hospitalization.

Yellowing of the skin or eyes

One of the other side effects that can occur with EVOTAZ 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, short of breath, or weakness in arms and legs
- allergic reaction - swelling of the face, lips, or throat which makes breathing difficult

These are very serious side effects. If you have them, you may have had a serious reaction to EVOTAZ. You may need urgent medical attention or hospitalisation.

This is not a complete list of side effects, other side effects not listed above may also occur in some patients.

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

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

After using EVOTAZ

Storage

Store EVOTAZ tablets in a cool dry place where the temperature stays below 25°C.

Keep your tablets in the bottle with the cap tightly closed until it is time to take them. If you take the tablets out of the bottle they may not keep as well.

Do not store EVOTAZ or any other medicine in the bathroom or near the kitchen sink. Do not leave EVOTAZ in the car or on a window sill. Heat and dampness can destroy some medicines.

Keep EVOTAZ tablets where children cannot reach them. 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 EVOTAZ tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

EVOTAZ tablets are oval, biconvex, pink film-coated, debossed on one side with "3641" and plain on the other side. Each bottle contains 30 tablets.

Ingredients

Each tablet contains:

Active ingredients:

- 300 mg atazanavir (as atazanavir sulfate) and 150 mg cobicistat per tablet

Other ingredients:

Microcrystalline cellulose, croscarmellose sodium, sodium starch glycolate, crospovidone, stearic acid, magnesium stearate, hydroxypropylcellulose, and silicon dioxide.

The film-coating is made from hypromellose, titanium dioxide, purified talc, glycerol triacetate, and red iron oxide.

Registration Numbers

EVOTAZ 300 mg atazanavir/150 mg cobicistat - AUST R 229476

Sponsored by

Bristol-Myers Squibb Australia Pty Ltd, 4 Nexus Court, Mulgrave, Victoria 3170, Australia

This information in no way replaces the advice of your doctor or pharmacist.

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