

EVOTAZ®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using EVOTAZ?

EVOTAZ contains the active ingredients atazanavir and cobicistat. EVOTAZ is used in combination with other anti-HIV agents to treat adults who are infected with Human Immunodeficiency Virus (HIV).

For more information, see Section [1. Why am I using EVOTAZ?](#) in the full CMI.

2. What should I know before I use EVOTAZ?

Do not use if you have ever had an allergic reaction to atazanavir, cobicistat or any of the ingredients listed at the end of the CMI.

Check with your doctor if you currently experience or have experienced liver problems including hepatitis, yellowing of the skin or eyes (jaundice) or prior use of medicines toxic to the liver. Talk to your doctor if you have any other medical conditions or

allergies, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use EVOTAZ?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with EVOTAZ and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use EVOTAZ?

- 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.

More instructions can be found in Section [4. How do I use EVOTAZ?](#) in the full CMI.

5. What should I know while using EVOTAZ?

Things you should do	
	<ul style="list-style-type: none">• Take EVOTAZ with food and at about the same time each day.• Remind any doctor, dentist or pharmacist

	<p>you visit that you are using EVOTAZ.</p> <ul style="list-style-type: none"> ● Make sure that you visit your doctor regularly throughout your entire course of treatment with EVOTAZ.
Things you should not do	<ul style="list-style-type: none"> ● Do not stop taking EVOTAZ without checking with your doctor. ● If you forget to take EVOTAZ, do not take a double dose.
Driving or using machines	<ul style="list-style-type: none"> ● 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.
Looking after your medicine	<ul style="list-style-type: none"> ● 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.

For more information, see Section [5. What should I know while using EVOTAZ?](#) in the full CMI.

6. Are there any side effects?

Common side effects can include headache, vomiting, diarrhoea, abdominal pain (stomach pain or discomfort), nausea, dyspepsia (indigestion or upset stomach), flatulence (wind), fatigue (extreme tiredness or loss of strength and energy), dizziness, insomnia.

Serious side effects can include tingling of the hands or feet, abdominal pain or tenderness, changes to the distribution of fat on your body, pain in joints, muscle pain, ulcers in the mouth, oesophagus (pain or burning on swallowing) or stomach (pain or indigestion), severe skin rash, changes in heart rhythm, fainting, yellowing of the skin or eyes, gallbladder disorders, kidney stones, liver problems, lactic acidosis, allergic reaction (swelling of the face, lips or throat).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

EVOTAZ® (ev-oh-taz)

Active ingredient(s): *Atazanavir* (ata-zan-a-vir) and *Cobicistat* (co-bi-ci-stat)

Consumer Medicine Information (CMI)

This leaflet provides important information about using EVOTAZ. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using EVOTAZ.**

Where to find information in this leaflet:

- [1. Why am I using EVOTAZ?](#)
- [2. What should I know before I use EVOTAZ?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use EVOTAZ?](#)
- [5. What should I know while using EVOTAZ?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using EVOTAZ?

EVOTAZ contains the 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 used in combination with other anti-HIV agents to treat adults who are infected with Human Immunodeficiency Virus (HIV). EVOTAZ is for adults.

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.

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.

2. What should I know before I use EVOTAZ?

Warnings

Do not use EVOTAZ if:

- You are allergic to atazanavir, cobicistat or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- You have liver disease.

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

- Other HIV medicines including other protease inhibitors (e.g. saquinavir, indinavir, elvitegravir, nevirapine, efavirenz, ritonavir)
- Antimycobacterial medicines 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 medicine containing salmeterol

- Cholesterol reducing medicines (lovastatin, simvastatin, lomitapide)
- Sleeping tablets containing midazolam or triazolam
- Medicines to treat psychotic problems containing pimozide or lurasidone
- Medicines to treat irregular heartbeats (e.g. dronedarone, quinidine)
- Calcium channel blockers (e.g. bepridil)
- Medicines to treat migraine or severe headaches which contain ergot derivatives (dihydroergotamine, ergonovine, ergotamine, methylergonovine)
- Herbal products which contain St John's wort (*Hypericum perforatum*)
- Medicines used to treat types of cancer (irinotecan, apalutamide, encorafenib, ivosidenib)
- Anticonvulsant medications (carbamazepine, phenytoin, phenobarbital) used to treat epilepsy
- 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.

Check with your doctor:

- **1) If you are taking any other HIV medicines**

- **2) If you 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) If you currently experience or have experienced any medical conditions especially:**

- Kidney problems or are undergoing kidney dialysis treatment
- Risk factors for chronic kidney disease including 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, haemophiliac 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.

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. EVOTAZ is not recommended for use during pregnancy.

Talk to your doctor if you are breastfeeding or planning to breastfeed. 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.

3. What if I am taking other medicines?

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

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 listed in Section [2. What should I know before I use EVOTAZ?](#)
- Medicines that may affect your kidneys unless you have discussed this with your doctor
- Other medicines to treat HIV (e.g. ritonavir, didanosine, tenofovir disoproxil fumarate, efavirenz, nevirapine, etravirine, rilpivirine, maraviroc, saquinavir, indinavir, other protease inhibitors)
- Medicines to treat hepatitis (e.g. telaprevir, boceprevir, sofosbuvir/velpatasvir/ voxilaprevir)
- Medicines to treat excessive sleepiness (e.g. modafinil)

- Medicines used to treat cancer (eg. dasatinib, nilotinib, vinblastine, vincristine)
- Medicines used to prevent blood clots (e.g. warfarin, dabigatran, apixaban, rivaroxaban, betrixaban, edoxaban, ticagrelor, clopidogrel, prasugrel)
- Medicines to treat certain heart conditions (e.g. 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 (e.g. clarithromycin, erythromycin) used to treat various infections
- Medicines to lower cholesterol (e.g. atorvastatin, rosuvastatin, pravastatin, fluvastatin)
- Antifungal medicines (e.g. ketoconazole, itraconazole, voriconazole) used to treat fungal infections
- Anticonvulsant medicines (e.g. clonazepam, ethosuximide) used to treat epilepsy
- Erectile dysfunction agents used to treat impotence (e.g. sildenafil, tadalafil, vardenafil).
- Medicines used to treat certain heart conditions (amiodarone, mexiletine, disopyramide, flecainide, propafenone, lignocaine, digoxin) or certain medicines

to treat depression and anxiety known as tricyclic antidepressants (e.g. amitriptyline, desipramine, imipramine, nortriptyline) - 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.

- Other antidepressants (e.g. paroxetine, trazodone)
- 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.
- 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.
- Medicines to suppress the immune system (e.g. cyclosporin, sirolimus, tacrolimus, rapamycin)
- Dexamethasone and other corticosteroids
- Medicines to treat psychiatric disorders (e.g. perphenazine, risperidone, thioridazine)
- Pain medicines (e.g. buprenorphine, naloxone, methadone, fentanyl, tramadol)
- Gout medicines (colchicine)
- Sedatives (e.g. midazolam, triazolam, buspirone, diazepam, zolpidem)
- Bosentan, a medicine used to treat pulmonary arterial hypertension

- Elagolix, a medicine used to treat pain associated with endometriosis in women
- Fostamatinib, a medicine used to treat low platelet counts due to chronic immune thrombocytopenia

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 medicines to treat your condition.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect EVOTAZ.

4. How do I use EVOTAZ?

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 EVOTAZ

- 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 EVOTAZ

- 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 EVOTAZ

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 EVOTAZ

If you think that you have used too much EVOTAZ, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using EVOTAZ?

Things you should do

- Make sure that you visit your doctor regularly throughout your entire course of treatment with EVOTAZ.
- If you plan to become pregnant or 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 should 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.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

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.

Looking after your medicine

- 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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● 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) ● Skin rash that may be severe ● Severe rash or a rash with flu-like illness symptoms, blisters, fever, mouth sores, muscle or joint pain, swelling in the face, inflammation of the eye 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>which causes redness (conjunctivitis), painful, warm, or red lumps (nodules)</p> <ul style="list-style-type: none"> ● Changes in heart rhythm, fainting ● Increased bleeding in haemophiliac patients ● Gallbladder disorders (which may include gallstones and gallbladder inflammation) - symptoms may include pain in the middle upper stomach, fever, nausea or vomiting, or yellowing of the skin (jaundice) and the whites of the eyes (scleral icterus) ● Kidney stones - symptoms may include pain in your side, blood in your urine, pain when you urinate ● Liver problems or a worsening of existing liver problems (including hepatitis B or C infection) - 	

Serious side effects	What to do
<p>symptoms may include yellowing of the skin or eyes, jaundice, vomiting, fever and dark coloured urine.</p> <ul style="list-style-type: none"> ● Lactic acidosis - symptoms may include nausea, vomiting, unusual or unexpected stomach discomfort, feeling very weak and tired, short of breath, or weakness in arms and legs ● Allergic reaction - symptoms may include a swelling of the face, lips or throat which makes breathing difficult. 	
<ul style="list-style-type: none"> ● Yellowing of your skin (jaundice) or the white part of your eyes (scleral icterus) 	<p>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.</p>

Other side effects

Common side effects	What to do
<ul style="list-style-type: none">• Headache• Vomiting, diarrhoea, abdominal pain (stomach pain or discomfort), nausea, dyspepsia (indigestion or upset stomach), flatulence (wind)• Fatigue (extreme tiredness or loss of strength and energy)• Dizziness, insomnia	Speak to your doctor if you have any of these side effects and they worry you.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What EVOTAZ contains

Active ingredients (main ingredients)	atazanavir (as atazanavir sulfate) and cobicistat
Other ingredients (inactive ingredients)	Microcrystalline cellulose, croscarmellose sodium, sodium starch glycolate, crospovidone, stearic acid, magnesium stearate, hydroxypropyl cellulose, and silicon dioxide. The film-coating is made from hypromellose, titanium dioxide, purified talc, glycerol triacetate, and red iron oxide.

Do not take this medicine if you are allergic to any of these ingredients.

What EVOTAZ tablets 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 (AUST R 229476).

Who distributes EVOTAZ

Bristol-Myers Squibb Australia Pty Ltd

4 Nexus Court, Mulgrave,

Victoria 3170, Australia

Toll free number: 1800 067 567

Email: MedInfo.Australia@bms.com

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