

REYATAZ®

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 REYATAZ?

REYATAZ contains the active ingredient atazanavir. REYATAZ 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).

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

2. What should I know before I use REYATAZ?

Do not use if you have ever had an allergic reaction to atazanavir 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 REYATAZ?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with REYATAZ 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 REYATAZ?

- If you are new to HIV treatment, your doctor may prescribe REYATAZ 400 mg (2 x 200 mg capsules) once a day with food OR REYATAZ 300 mg once daily with ritonavir (100 mg daily) taken with food. If you have been on previous HIV treatment, the usual dose is REYATAZ 300 mg once daily with ritonavir (100 mg daily) taken with food. If you are between the ages of 6 and 18 years old, the dose of REYATAZ will be different. Your doctor will tell you what dose of REYATAZ you should take.

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

5. What should I know while using REYATAZ?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using REYATAZ.• Make sure that you visit your doctor regularly throughout your entire course of treatment with REYATAZ.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking REYATAZ without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how REYATAZ affects you.• Some patients taking REYATAZ have experienced dizziness. It is not known if this was caused by REYATAZ.
Looking after your medicine	<ul style="list-style-type: none">• Store REYATAZ capsules 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 REYATAZ?](#) 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.

REYATAZ[®] (ray-uh-taz)

Active ingredient(s): *Atazanavir* (ata-zan-a-vir)

Consumer Medicine Information (CMI)

This leaflet provides important information about using REYATAZ. **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 REYATAZ.**

Where to find information in this leaflet:

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

1. Why am I using REYATAZ?

REYATAZ contains the active ingredient atazanavir.

REYATAZ belongs to a group of medicines called protease inhibitors.

REYATAZ 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 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.

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

REYATAZ 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 REYATAZ has been prescribed for you.

REYATAZ is not addictive.

2. What should I know before I use REYATAZ?

Warnings

Do not use REYATAZ if:

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

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

- Rifampicin - a medicine used to treat tuberculosis
- Sildenafil - if you are taking it for pulmonary arterial hypertension
- Medicines used to treat types of cancer (irinotecan, apalutamide, encorafenib, ivosidenib)
- Cisapride - a medicine used to treat gastric reflux
- Alfuzosin - a medicine used in bladder disorders
- Anticonvulsant medications (carbamazepine, phenytoin, phenobarbital) used to treat epilepsy
- Asthma medications (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 migraine or severe headaches which contain ergotamine
- Herbal products which contain St John's wort (*Hypericum perforatum*)
- Protease inhibitor (indinavir)
- Medicines to treat hepatitis C containing elbasvir/grazoprevir or glecaprevir/pibrenstasvir
- If you are taking REYATAZ with another medicine for the treatment of HIV called ritonavir, then you should not take certain medicines such as calcium channel blockers such as 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 use REYATAZ 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 REYATAZ if the packaging is torn or shows signs of tampering.

Check with your doctor:

1) If you have allergies to:

- other medicines that are called 'protease inhibitor'
- 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.

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

- 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 REYATAZ in the blood, increasing the chance of side effects
- 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
- Haemophilia. Haemophiliac patients may experience increased bleeding when taking REYATAZ
- 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 REYATAZ.

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

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

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

It is not known whether REYATAZ passes into breast milk. Therefore to avoid possible side effects in the nursing infant, mothers should stop breast-feeding if they are taking REYATAZ (breast-feeding can also transfer HIV to babies).

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:

REYATAZ will be given with other anti-HIV medicines, some of these anti-HIV medicines may affect the way REYATAZ works, and REYATAZ 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 to treat hepatitis (e.g. telaprevir, bocepravir, 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 REYATAZ. 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 medication (lamotrigine) used to treat epilepsy
- Erectile dysfunction agents used to treat impotence - 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 REYATAZ 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 REYATAZ. These medicines should be taken one hour before or two hours after REYATAZ.
- Drugs that affect the electrical activity of the heart
- Oral contraceptives - REYATAZ 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, a medication used to treat pulmonary arterial hypertension.
- Anticoagulant medications including warfarin, betrixaban, dabigatran, edoxaban, rivaroxaban and apixaban
- Medications used to prevent blood clots - ticagrelor, clopidogrel and prasugrel
- Medications used to treat certain types of cancer - apalutamide, encorafenib and ivosidenib
- Dexamethasone and other corticosteroids

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 REYATAZ.

Your doctor will be able to advise you about the most appropriate medications 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 REYATAZ.

4. How do I use REYATAZ?

How much to take

- If you are new to HIV treatment, your doctor may prescribe REYATAZ 400 mg (2 x 200 mg capsules)

once a day with food OR REYATAZ 300 mg once daily with ritonavir (100 mg daily) taken with food.

- If you have been on previous HIV treatment, the usual dose is REYATAZ 300 mg once daily with ritonavir (100 mg daily) taken with food.
- Your doctor will tell you what dose of REYATAZ you should take.
- If you are between the ages of 6 and 18 years old, the dose of REYATAZ will be different. Please follow your doctor's instructions.
- Follow the instructions provided and use REYATAZ until your doctor tells you to stop.

How to take REYATAZ

- Swallow the capsules whole with a drink such as a glass of water or fruit juice. The dose of REYATAZ should be taken with food.

When to take REYATAZ

- You may take REYATAZ Capsules at any time. It is recommended, however, that you take your medicine at about the same time each day. Taking REYATAZ at the same time each day will have the best effect. It will also help you remember when to take the capsules.
- Talk to your doctor or pharmacist to work out when it is best for you to take your doses of REYATAZ.

How long to take REYATAZ

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

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

If you forget to take REYATAZ

If it is almost time for your next dose, skip the dose you missed and take your 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 REYATAZ. If you miss doses the virus may become resistant to your HIV medicines.

If you take too much REYATAZ

If you think that you have used too much REYATAZ, 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 REYATAZ?

Things you should do

- Make sure that you visit your doctor regularly throughout your entire course of treatment with REYATAZ.
- If you plan to become pregnant or become pregnant while taking REYATAZ, tell your doctor immediately. Pregnant women have experienced serious side effects when taking atazanavir (the active ingredient in REYATAZ) in combination with didanosine and stavudine.
- If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking

REYATAZ. REYATAZ may interfere with the medicine you are taking.

- If you are about to have any medical tests, tell your doctor that you are taking REYATAZ. REYATAZ may interfere with the results of these tests.
- If you plan to have surgery, tell your doctor or dentist that you are taking REYATAZ. You may wish to discuss disclosure issues with your doctor about who should know you are taking REYATAZ.
- 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 REYATAZ is working.

Things you should not do

- Do not give REYATAZ to anyone else, even if they have the same condition as you.
- Do not use REYATAZ to treat any other complaints unless your doctor tells you to.
- Do not stop taking REYATAZ without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how REYATAZ affects you.

Some patients taking REYATAZ have experienced dizziness. It is not known if this was caused by REYATAZ. Make sure you know how you react to REYATAZ 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 REYATAZ capsules in a cool dry place where the temperature stays below 25°C.
- Keep 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 as well.
- Do not store REYATAZ or any other medicine in the bathroom or near the kitchen sink. Do not leave it in the car. Heat and dampness can destroy some medicines.

- Keep REYATAZ capsules 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 your doctor tells you that 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 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● 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 which causes redness (conjunctivitis), painful, warm, or red lumps (nodules) ● Changes in heart rhythm, fainting ● Increased bleeding in haemophiliac patients ● Gallbladder disorders (which may include gallstones) 	<p>notice any of these serious side effects.</p>

Serious side effects	What to do
<p>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)</p> <ul style="list-style-type: none"> ● 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) - symptoms may include yellowing of the skin or eyes, jaundice, vomiting, fever and dark coloured urine. ● Lactic acidosis - symptoms may include nausea, vomiting, unusual or unexpected stomach discomfort, feeling very weak and 	

Serious side effects	What to do
<p>tired, short of breath, or weakness in arms and legs</p> <ul style="list-style-type: none"> ● 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) 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Common side effects	What to do
or upset stomach), flatulence (wind) <ul style="list-style-type: none"> • Fatigue (extreme tiredness or loss of strength and energy) • Dizziness, insomnia 	

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 REYATAZ contains

Active ingredient (main ingredient)	atazanavir as the sulfate
Other ingredients (inactive ingredients)	Lactose monohydrate, crospovidone and magnesium stearate. The capsule shell is made from gelatin, titanium dioxide and FD&C blue#2; the 300 mg capsule shell also contains red iron oxide, black iron oxide and yellow iron oxide
Potential allergens	Lactose monohydrate

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

What REYATAZ capsules look like

REYATAZ 200 mg capsules - blue capsules, marked "BMS 200 mg" and "3631" in white, 200 mg of atazanavir as the sulfate per capsule; 60 capsules per bottle (AUST R 99056)

REYATAZ 300 mg capsules - red and blue capsules, marked "BMS 300 mg" and "3622" in white; 300 mg of atazanavir as the sulfate per capsule; 30 capsules per bottle (AUST R 134967)

Who distributes REYATAZ

Bristol-Myers Squibb Australia Pty Ltd

4 Nexus Court, Mulgrave,

Victoria 3170, Australia

Toll free number: 1800 067 567

Email: MedInfo.Australia@bms.com

REYATAZ® is a registered trademark of Bristol-Myers Squibb Company.

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