

TRIZIVIR

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.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I taking TRIZIVIR?

TRIZIVIR contains the active ingredients abacavir, lamivudine and zidovudine. TRIZIVIR is used, alone or in combination with other antiretrovirals, to slow down the progression of human immunodeficiency virus (HIV) infection which can lead to Acquired Immune Deficiency Syndrome (AIDS) and other related illnesses (e.g. AIDS-related Complex (ARC)).

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

2. What should I know before I take TRIZIVIR?

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

IF YOU EXPERIENCE AN ALLERGIC REACTION TO TRIZIVIR IMMEDIATELY STOP TAKING THIS MEDICINE AND SEEK MEDICAL ATTENTION. THIS MAY BE LIFE-THREATENING.

Talk to your doctor if you have any other medical conditions, 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 take TRIZIVIR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TRIZIVIR 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 take TRIZIVIR?

- The usual dosage of TRIZIVIR tablets is one tablet twice a day. Swallow the tablets with some water.

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

5. What should I know while taking TRIZIVIR?

Things you should do	<ul style="list-style-type: none">● Remind any doctor, dentist or pharmacist you visit that you are taking TRIZIVIR.● For as long as you are taking TRIZIVIR, your doctor will arrange for you to have regular blood tests to check for side effects.● Keep in contact with your doctor and don't stop taking TRIZIVIR without talking to your doctor.
Things you should not do	<ul style="list-style-type: none">● Do not stop using this medicine or change the dose without talking to your doctor unless you experience an allergic reaction.● Do not take this medicine to treat any other complaints.

<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● Be careful before you drive or use any machines or tools until you know how TRIZIVIR affects you.
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> ● Store TRIZIVIR below 30°C in the pack out of direct light. ● Keep this medicine in the pack until it is time to take it.

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

6. Are there any side effects?

Side effects that have been reported include body odour, chills, increased sensitivity to pain, back pain, chest pain, weakness, weight loss, loss of appetite, generally feeling unwell, feeling faint, constipation, diarrhoea, difficulty in swallowing, mouth ulcers, bleeding gums, heartburn, vomiting, nausea, muscle aches and spasms, confusion, depression, nervousness, loss of mental clarity, dizziness, headache, sleeplessness, cough, sore throat, hay fever, itchiness, vision problems, sensitivity to light, ,increased frequency of urination, anaemia, neutropenia, allergic reactions, pancreatitis, lipoatrophy and lactic acidosis.

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.

WARNING: PATIENTS TAKING TRIZIVIR, WHICH CONTAINS ABACAVIR, MAY DEVELOP A HYPERSENSITIVITY REACTION (SERIOUS ALLERGIC REACTION) WHICH CAN BE LIFE-THREATENING IF TREATMENT WITH TRIZIVIR IS CONTINUED. CONTACT YOUR DOCTOR IMMEDIATELY FOR ADVICE ON WHETHER YOU SHOULD STOP TAKING TRIZIVIR IF:

- 1. YOU GET A SKIN RASH or**
- 2. YOU GET ONE OR MORE SYMPTOMS FROM AT LEAST TWO OF THE FOLLOWING GROUPS:**

- FEVER

- SHORTNESS OF BREATH, SORE THROAT OR COUGH

- NAUSEA, VOMITING, DIARRHOEA OR ABDOMINAL PAIN

- SEVERE TIREDNESS, ACHINESS OR GENERALLY FEELING UNWELL

IF YOU HAVE HAD A HYPERSENSITIVITY (ALLERGIC) REACTION TO TRIZIVIR TABLETS, NEVER TAKE TRIZIVIR OR ANY OTHER MEDICINE CONTAINING ABACAVIR (Kivexa, Triumeq, Ziagen) AGAIN AS YOU MAY DEVELOP A LIFE-THREATENING REACTION WHICH CAN BE FATAL.

THERE IS AN ALERT CARD INCLUDED IN THE TRIZIVIR PACK TO REMIND YOU AND MEDICAL STAFF ABOUT ABACAVIR HYPERSENSITIVITY.

THIS CARD SHOULD BE REMOVED FROM THE PACK AND KEPT WITH YOU AT ALL TIMES.

SEE MORE DETAILS UNDER SECTION 2. WHAT SHOULD I KNOW BEFORE I TAKE TRIZIVIR.

TRIZIVIR

Active ingredients: *abacavir, lamivudine and zidovudine*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking TRIZIVIR?

TRIZIVIR contains the active ingredients abacavir, lamivudine and zidovudine. TRIZIVIR belongs to a group of medicines called antiretrovirals.

TRIZIVIR is used, alone or in combination with other antiretrovirals, to slow down the progression of human immunodeficiency virus (HIV) infection which can lead to Acquired Immune Deficiency Syndrome (AIDS) and other related illnesses (e.g. AIDS-related Complex (ARC)).

TRIZIVIR does not cure AIDS or HIV infection however it slows down production of HIV in the body. In this way it stops ongoing damage to the body's immune system which fights infection.

You can still pass on HIV when taking this medicine through sexual activity or through passing on blood or bodily secretions which carry the HIV virus, although the risk is lowered by taking antiretroviral therapy.

You should use proper precautions to prevent this from occurring. Discuss with your doctor the precautions needed to avoid infecting other people.

While taking TRIZIVIR and/or any other therapy for HIV, you may continue to develop other infections and other complications of HIV infection. You should keep in regular contact with your doctor.

TRIZIVIR is a combination medicine and may be available separately in some countries: abacavir alone is called ZIAGEN (tablets and oral solution),

lamivudine alone is called 3TC (tablets and oral solution) and zidovudine alone is RETROVIR (tablets and oral solution).

2. What should I know before I take TRIZIVIR?

Warnings

HYPERSENSITIVITY REACTION

Patients taking TRIZIVIR may develop a hypersensitivity reaction (serious allergic reaction) which can be life-threatening if you continue to take TRIZIVIR. It is important that you read the information on this reaction in this section of the leaflet. There is also an alert card included in the TRIZIVIR pack to remind you and medical staff about TRIZIVIR hypersensitivity. This card should be removed from the pack and kept with you at all times.

The symptoms of this reaction include fever, nausea or vomiting or diarrhoea or abdominal pain, skin rash or skin redness or itching, severe tiredness or body aches or generally feeling unwell, shortness of breath or sore throat or cough.

If you develop any of these symptoms call your doctor IMMEDIATELY WHO WILL ADVISE YOU WHETHER TO STOP TAKING TRIZIVIR. If your doctor is not available, you must urgently seek other medicinal advice (e.g. by going to the Emergency

Department at your nearest hospital) before taking the next dose.

If you have had this reaction to TRIZIVIR, NEVER take TRIZIVIR or any other medicines containing abacavir (Kivexa, Triumeq, Ziagen) again as WITHIN HOURS you may experience a life-threatening lowering of your blood pressure or death.

Other symptoms may include joint or muscle pain, swelling of the neck or itchy skin. Occasionally inflammation of the eye (conjunctivitis), ulcers in the mouth, tingling or numbness of the hands or feet or low blood pressure may occur. The symptoms of this allergic reaction can occur at any time during treatment. It usually occurs within the first six weeks of treatment with abacavir, and gets worse with continued treatment.

Occasionally life-threatening hypersensitivity reactions have occurred when abacavir was restarted in patients who reported only one of the symptoms on the Alert Card.

On very rare occasions, hypersensitivity has been reported when abacavir was re-started in patients who had no symptoms of hypersensitivity before stopping.

Research has found that people with a gene called HLA-B (type 5701) are more likely to have a hypersensitivity reaction to abacavir. However, even if you do not have this gene, it is still possible for you to get this reaction. If you know you have this

gene, be sure to tell your doctor before you take abacavir.

Do not use TRIZIVIR if:

- you are allergic to abacavir (trade name Ziagen or any other abacavir containing products Kivexa, Triumeq), lamivudine (trade name 3TC) or zidovudine (trade name Retrovir), or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- **TELL YOUR DOCTOR IMMEDIATELY IF YOU EXPERIENCE AN ALLERGIC REACTION.**
- **YOU MUST NOT TAKE TRIZIVIR OR ANY OTHER MEDICINE CONTAINING ABACAVIR (Kivexa, Triumeq, Ziagen) AGAIN.**
- you have a reduced red blood cell count (anaemia) or white blood cell count (neutropenia).
- you have kidney disease or severe liver disease.
- you are pregnant, think you may be pregnant or are breastfeeding.

Check with your doctor if you:

- have any other medical conditions or illnesses and any not related to HIV infection
- take any medicines for any other condition
- are allergic to any other foods, dyes, preservatives or medicines
- are taking riociguat (e.g. Adempas; a medicine used to treat high blood pressure in the arteries that carry

blood from the heart to the lungs) as your doctor may need to reduce the dose of riociguat. Abacavir (one of the active ingredients in TRIZIVIR) may increase the level of riociguat in your blood

- have or have ever had a hepatitis B infection
- have or have ever had liver problems (e.g. jaundice, hepatitis, a virus affecting the liver, an enlarged liver, liver scarring (cirrhosis)) or if you have any risk factors for liver problems (e.g. excessive alcohol intake, use illegal intravenous drugs with shared equipment or have iron or copper storage disorders)

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

Talk to your doctor if you are pregnant or intend to become pregnant.

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

Your doctor can discuss with you the benefits and risks of taking TRIZIVIR whilst pregnant or breastfeeding.

Children and adolescents

TRIZIVIR is not recommended for use in children or adolescents who weigh less than 40 kg. TRIZIVIR is a fixed dose combination tablet and- as such it cannot be adjusted according to the size and weight of the patient.

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.

Some medicines may interfere with TRIZIVIR and affects how it works.

If you take ribavirin (e.g. Ibavyr) and TRIZIVIR together it may cause or worsen anaemia (low red blood cells). Tell your doctor if you notice symptoms of anaemia such as tiredness and shortness of breath.

Tell your doctor if you are taking any of the following medicines:

- phenytoin, a medicine used to treat epilepsy
- oxazepam, lorazepam; medicines used to treat anxiety and insomnia
- aspirin, codeine, morphine, methadone, indomethacin, ketoprofen, naproxen – medicines used to treat pain
- cimetidine, a medicine used to treat heartburn, stomach ulcers
- clofibrate, a medicine used to treat high cholesterol, high triglycerides
- probenecid, a medicine used to treat gout
- isoprinosine, ganciclovir, interferons, ribavirin; antiviral medicines
- stavudine, emtricitabine; medicines used to treat HIV
- pentamidine, atovaquone; antimicrobial medicines

- pyrimethamine, dapsone; medicines used to treat parasite infections
- flucytosine, a medicine used to treat fungal infections
- clarithromycin, trimethoprim/sulfamethoxazole, medicines used to treat bacterial infections
- vincristine, vinblastine, doxorubicin; medicines used in the treatment of cancer
- sorbitol-containing medicines (usually liquids) which are used regularly

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

4. How do I take TRIZIVIR?

How much to take

- The usual dosage of TRIZIVIR tablets is one tablet twice a day.
- If you have certain medical conditions, your doctor may advise that you take a lower dose of abacavir, lamivudine and/or zidovudine, the active ingredients in TRIZIVIR.
- Follow the instructions provided and use TRIZIVIR until your doctor tells you to stop.

How to take TRIZIVIR

- Swallow the tablets whole with a drink of water.

If you forget to take TRIZIVIR

TRIZIVIR should be taken regularly at the same time each day.

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

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

If you take too much TRIZIVIR

If you think that you have used too much TRIZIVIR, 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 taking TRIZIVIR?

Things you should do

Tell your doctor straight away if you:

- have any sign of an allergic reaction or have experienced an allergic reaction in the past to any medicine containing abacavir (e.g. Kivexa, Triumeq, Ziagen)
- become pregnant or intend to become pregnant
- have not taken TRIZIVIR as intended

Remind any doctor, dentist or pharmacist you visit that you are taking TRIZIVIR.

This is especially important for any medicines that might have an effect on your liver, kidneys, red or white blood cells or other cells in the body.

Stay in regular contact with your doctor

TRIZIVIR helps to control your condition, but it is not a cure for HIV infection. You need to keep taking it every day to stop your illness from getting worse. Because TRIZIVIR does not cure HIV infections, you may still develop other infections and illnesses linked to HIV.

Whilst you are taking TRIZIVIR it is important to have blood tests when your doctor asks you to. This enables them to check your health and monitor the levels of your red and white blood cells. If you develop anaemia or

neutropenia, your doctor may reduce the dose or stop treatment with TRIZIVIR.

If you stop taking TRIZIVIR

If you have a long-standing infection of your liver (hepatitis B) it may flare up. This can cause serious illness particularly if your liver is already not working very well. If you have both HIV and hepatitis B, when you stop taking TRIZIVIR, your doctor is likely to arrange tests to check how well your liver is working and to measure virus levels.

Things you should not do

- Do not stop taking this medicine or change the dose.
- **If you have stopped taking TRIZIVIR for any reason it is important that you contact your doctor before restarting. This is very important if you think you are experiencing side effects from other medicines or have another illness.**
- **Your doctor will check whether any symptoms you had before stopping this medicine may be related to a hypersensitivity reaction.**
- **If your doctor thinks there was a possibility that they were related, you may be told to never take TRIZIVIR or any other medicine containing abacavir (Kivexa, Triumeq, Ziagen) again. It is important to follow this advice.**
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

- Do not use this medicine to treat any other complaints unless your doctor tells you to.

Driving or using machines

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

TRIZIVIR may cause headaches and tiredness in some people.

Looking after your medicine

- Keep TRIZIVIR in the pack until it is time to take it. Store it in a cool dry place (below 30°C) away from moisture, heat or sunlight; for example, do not store it:
 - in the bathroom or near a sink, or
 - in the car or on window sills.

Keep it where young children cannot reach it.

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.

If you become concerned about any new symptoms, or any changes in your health after starting HIV treatment, discuss with your doctor immediately.

It is not known whether these side effects are due to taking TRIZIVIR or taking TRIZIVIR whilst taking other medicines. Some of these side effects may occur as part of HIV infection, AIDS or AIDS-related Complex.

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

Hypersensitivity reaction

TRIZIVIR contains abacavir (which is also an active ingredient in Kivexa, Triumeq and Ziagen).

Abacavir can cause a serious allergic reaction known as a hypersensitivity reaction, which can be life-threatening if treatment with abacavir containing products is not stopped. This reaction is described in the Section 2 [What should I know before I take TRIZIVIR?](#) It is important that you read and understand the information about this serious reaction.

Within the first few weeks of treatment with anti-HIV medicines, some people, particularly those that have been HIV positive for some time, may develop inflammatory reactions (e.g. pain, redness, swelling, high temperature) which may resemble an infection and may be severe. It is thought that these reactions are caused by a recovery in the body's ability to fight infections, previously suppressed by HIV.

Less serious side effects

Less serious side effects	What to do
<p>Psychiatric disorders:</p> <ul style="list-style-type: none"> ● confusion, depression, nervousness, loss of mental clarity, <p>Nervous system disorders:</p> <ul style="list-style-type: none"> ● dizziness, seizures, headache, fainting, sleeplessness, fatigue, tiredness ● unusual feelings in any part of the body, such as numbness, burning, tingling or pins and needles ● vision problems, sensitivity to light <p>Blood system disorders:</p> <ul style="list-style-type: none"> ● widening of blood vessels leading to low blood pressure and feeling faint ● increased bruising or bleeding <p>Metabolic disorders:</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● weight loss, loss of appetite <p>Respiratory disorders:</p> <ul style="list-style-type: none"> ● cough, sore throat, hay fever, sinus problems, hoarseness ● ear, nose, throat infections <p>Gastrointestinal disorders:</p> <ul style="list-style-type: none"> ● constipation, gas from the stomach or bowel, blood in the stool, diarrhoea, abdominal discomfort and pain ● vomiting, nausea ● heartburn ● difficulty in swallowing, mouth ulcers, bleeding gums <p>Skin disorders:</p> <ul style="list-style-type: none"> ● acne, itchiness, changes in nail, skin or mouth colour <p>Musculoskeletal disorders:</p>	

Less serious side effects	What to do
<ul style="list-style-type: none"> ● muscle aches or pains, muscle shaking or spasms or twitching <p>Urinary disorders:</p> <ul style="list-style-type: none"> ● passing too much urine or increased frequency of urination <p>General disorders:</p> <ul style="list-style-type: none"> ● generally feeling unwell ● chills, fever ● flu like symptoms ● increased sensitivity to pain, back pain, enlarged glands, chest pain ● discomfort and pain <p>Side effects that may show up in blood tests:</p> <ul style="list-style-type: none"> ● abnormal results of blood tests of liver function ● reduction in blood cells ● blood chemistry changes, with excess acidity of the blood <p>Other:</p> <ul style="list-style-type: none"> ● body odour 	

Less serious side effects	What to do
<ul style="list-style-type: none"> ● hearing loss ● hair loss 	

Serious side effects

Serious side effects	What to do
<p>Blood system disorders:</p> <ul style="list-style-type: none"> ● reduced red blood cell count (anaemia) ● reduced white blood cell count (neutropenia) <p>The frequency and severity of anaemia and neutropenia are greater in patients with advanced HIV disease or in patients who start taking TRIZIVIR in the later stages of HIV disease.</p> <p>Allergic reactions:</p> <ul style="list-style-type: none"> ● serious skin reactions ● swelling of the lips, tongue, wheezing or difficulty breathing, rash, hives on the skin. 	<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>These are all signs of an allergic reaction</p> <p>Pancreatitis:</p> <ul style="list-style-type: none"> • signs of an inflamed pancreas (pancreatitis) such as severe stomach pain or cramps, nausea, vomiting <p>If you experience any of these symptoms soon after starting treatment with TRIZIVIR stop taking this medicine and contact your doctor immediately.</p> <p>Change in body shape:</p> <p>Treatment with TRIZIVIR may cause a loss of fat from the legs, arms and face (lipoatrophy). If this occurs tell your doctor and they will assess if you should stop taking TRIZIVIR and your HIV treatment be changed. If you stop taking TRIZIVIR it may take several months to see any lost fat return and you might not regain it all.</p>	

Serious side effects	What to do
<p>Lactic acidosis: If you are taking medication for HIV and become unwell with fast breathing, stop taking TRIZIVIR and talk to your doctor immediately. This might be a condition known as 'lactic acidosis'. The fast breathing is due to high acid levels in the blood. Your liver may not be working properly and gets big and fatty and can be life threatening. This illness occurs more often in women than men.</p>	

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 TRIZIVIR contains

Active ingredients (main ingredients)	abacavir (as sulfate) lamivudine zidovudine
Other ingredients (inactive ingredients)	aluminium lake hypromellose indigo carmine CI73015 iron oxide yellow macrogol 400 magnesium stearate microcrystalline cellulose sodium starch glycolate titanium dioxide

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

What TRIZIVIR looks like

TRIZIVIR tablets are blue/green capsule-shaped film-coated tablets, engraved with "GX LL1" on one tablet face. Available in packs of 60 tablets.

AUST R 78348 (bottle)

AUST R 78349 (blister pack)

Who distributes TRIZIVIR

ViiV Healthcare Pty Ltd

Level 4, 436 Johnson Street

Abbotsford VIC 3067

Australia

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