TRIZIVIR

film coated tablets

abacavir (as sulfate), lamivudine and zidovudine

Consumer Medicine Information

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 OR VOMITING OR DIARRHOEA OR ABDOMINAL PAIN
- SEVERE TIREDNESS OR ACHINESS OR GENERALLY ILL FEELING
IF YOU HAVE HAD A HYPERSENSITIVITY (ALLERGIC) REACTION TO TRIZIVIR TABLETS, NEVER TAKE TRIZIVIR, OR ANY OTHER MEDICINAL PRODUCT 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 BEFORE YOU TAKE TRIZIVIR.

What is in this leaflet?

Please read this leaflet carefully before you start TRIZIVIR tablets.

This leaflet answers some common questions about TRIZIVIR tablets. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist (also known as a chemist).

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you taking TRIZIVIR tablets against the risks this medicine could 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.

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 you read the information on this reaction in the section "Special Warning" under "Before you take TRIZIVIR tablets", of this 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 ill; shortness of breath, sore throat or cough. If you develop any of these symptoms call your doctor IMMEDIATELY WHO WILL ADVISE YOU WHETHER YOU SHOULD STOP TAKING TRIZIVIR. If your doctor is not available you must urgently seek other medical advice (eg. the Accident and Emergency unit of the nearest hospital) before taking the next dose.

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

What TRIZIVIR tablets are used for

TRIZIVIR contains abacavir, lamivudine and zidovudine which each belong to a group of medicines called antiretrovirals.

Please note that these medicines may also be available separately in some countries: abacavir (as sulfate) alone is ZIAGEN (tablets and oral solution), lamivudine alone is 3TC, (tablets and oral solution) and zidovudine alone is RETROVIR (capsules and syrup).

TRIZIVIR is used, alone or 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 or ARC).

TRIZIVIR does not cure AIDS or HIV infection, but prevents further damage to the body's immune system by stopping production of new viruses.

TRIZIVIR does not reduce your risk of passing HIV infection to others. You will still be able to pass on the HIV virus by sexual activity or by contamination with infected blood. You should use proper precautions to prevent this.

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

TRIZIVIR is not addictive.

Before you take TRIZIVIR tablets

Do not take if:

You must not take TRIZIVIR tablets if:

- **you have ever had an allergic reaction to either**
  - abacavir (trade name ZIAGEN) or any other abacavir containing products (KIVEXA, TRIUMEQ),
  - lamivudine (trade name 3TC),
  - zidovudine (trade name RETROVIR)
  - a product containing both lamivudine and zidovudine (trade name COMBIVIR), or
  - any of the ingredients listed at the end of this leaflet.

Special warning

TRIZIVIR contains abacavir. 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.

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 type it is still possible for you to get this reaction. If you know you have this gene type, be sure to tell your doctor before you take abacavir.

The most common symptoms of this reaction include high temperature (fever) and a skin rash. Other most frequently seen symptoms include; nausea, vomiting, diarrhoea or abdominal pain; severe tiredness or body aches or generally feeling ill; headache; shortness of breath, sore throat or cough. If you develop any of these symptoms call your doctor IMMEDIATELY WHO WILL ADVISE YOU WHETHER YOU SHOULD STOP TAKING TRIZIVIR. If your doctor is not available you must urgently seek other medical advice (eg. the Accident and Emergency unit of the nearest hospital) before taking the next dose.

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 which usually occur in the first six weeks of treatment with abacavir, and get worse with continued treatment.

If you have had this serious reaction to TRIZIVIR, NEVER take TRIZIVIR or any other medicine containing abacavir (KIVEXA, TRIUMEQ, ZIAGEN) again as within hours you may experience a life-threatening lowering of your blood pressure or death.

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

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

If you have stopped taking TRIZIVIR for any reason it is important that you contact

your doctor before restarting. This is especially so if you think you are having side-effects from other medicines or have another illness. Your doctor will check whether any symptoms you had before stopping may be related to this hypersensitivity reaction. If your doctor thinks there is a possibility that they were related, you may be told never to take TRIZIVIR, or any other medicine containing abacavir (KIVEXA, TRIUMEQ, ZIAGEN) again. It is important that you follow this advice.

If you are hypersensitive to TRIZIVIR you should return all of your unused TRIZIVIR to your doctor or pharmacist for proper disposal.

You must not take TRIZIVIR tablets if:

- you develop any of the symptoms of allergy or hypersensitivity tell your doctor immediately. If an allergy or hypersensitivity is suspected then your doctor will stop your TRIZIVIR treatment.
  YOU MUST NOT TAKE TRIZIVIR,OR ANY OTHER MEDICINE CONTAINING ABACAVIR (KIVEXA, TRIUMEQ, ZIAGEN) AGAIN.
- **you are pregnant, think you may be pregnant, are breastfeeding, unless your doctor tells you to.**
- **you have**
  - kidney disease
  - severe liver disease
  - reduced red blood cell count (anaemia)
  - reduced white blood cell count (neutropenia)
  If you have certain conditions, your doctor may advise that you take a lower dose of abacavir, lamivudine and/or zidovudine, the active ingredients in TRIZIVIR tablets. Although not available in all countries, abacavir may be available separately as ZIAGEN tablets and oral solution, lamivudine as 3TC tablets and oral solution, and zidovudine is available as RETROVIR capsules and syrup. Ask your doctor if you are not sure whether you should take TRIZIVIR.
- **the expiry date (EXP) printed on the pack has passed.**
- **the packaging is torn or shows signs of tampering.**

If you take ribavirin and TRIZIVIR together it may cause or worsen anaemia. Please contact your doctor if you notice symptoms of anaemia (such as tiredness and shortness of breath). Your doctor will advise you whether you should stop taking TRIZIVIR.

Tell your doctor if:

You must tell your doctor if:

- **in the past you have had a allergic reaction to medicines containing abacavir (KIVEXA, TRIUMEQ, TRIZIVIR, ZIAGEN).**
- **you are allergic to foods, dyes, preservatives or any other medicines.**
- **you are taking or have taken any other medicines, including medicines you buy without a prescription.**
- **you have, or have ever had, hepatitis B infection.**
- **you have, or have ever had, liver problems, for example jaundice, hepatitis, virus affecting the liver, enlarged liver or liver scarring (cirrhosis) or if you have any risk factors for liver problems, e.g. excessive alcohol intake, illegal intravenous drug use with shared equipment, iron or copper storage disorders.**
- **you have any other illness, including those that you think are not related to HIV infection.**
- **If you are taking any of the medicines below:**
  - Phenytoin, oxazepam, lorazepam.
  - Aspirin, codeine, morphine, methadone, indomethacin, ketoprofen, naproxen, cimetidine, clofibrate, probenecid, isoprinosine.
  - Pentamidine, pyrimethamine, dapsone, atovaquone, amphotericin, flucytosine, ganciclovir, interferon, clarithromycin.
  - Vincristine, vinblastine and doxorubicin
  - ribavirin
  - stavudine, or zalcitabine or emtricitabine
  - co-trimoxazole
  - sorbitol-containing medicines (usually liquids) used regularly

Use in children and adolescents

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

How do I take TRIZIVIR tablets?

How much to take

Take TRIZIVIR tablets as directed by your doctor or pharmacist. The usual dosage of TRIZIVIR tablets is one tablet, twice a day. Your doctor may prescribe a different dosage.

How to take them

Your TRIZIVIR tablets should be swallowed with a drink of water.

How long to take them

Because your medicine helps to control your condition, but does not cure it, you will need to take the tablets every day. Do not stop taking your medicine without first talking to your doctor.

What do I do if I take too much? (Overdose)

If you think you or anyone else may have taken too many TRIZIVIR tablets, immediately telephone your doctor or Poisons Information Centre (in Australia telephone 131126. In New Zealand telephone 0800 POISON or 0800 764 766) or go to the Accident and Emergency unit at your nearest hospital. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking TRIZIVIR tablets

Things you must do

Tell your doctor or pharmacist that you are taking TRIZIVIR tablets if you are about to be started on any new medicines. There is little information about the way other medicines might affect the way that TRIZIVIR works. You must tell your doctor or pharmacist that you are taking TRIZIVIR before you start taking medicines you buy from a pharmacy, health food shop or supermarket. This is especially important regarding medicines which might have an effect on the kidneys, liver, red or white blood cells or other body cells.

Tell your doctor if you become pregnant or think you are pregnant.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.
Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

If you forget to take them

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, then go back to taking it as you would normally.

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

If you have stopped taking them

If you have a long-standing viral 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 your TRIZIVIR tablets, your doctor is likely to arrange tests from time to time to check how well your liver is working and to measure virus levels.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use TRIZIVIR tablets to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how TRIZIVIR tablets affect you.

TRIZIVIR tablets taken alone generally do not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, TRIZIVIR tablets may cause headache and tiredness in some people.

What are the side-effects?

Check with your doctor as soon as possible if you have any problems while taking TRIZIVIR tablets, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like all medicines, TRIZIVIR tablets can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

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 "Special warning" under "Before you take TRIZIVIR tablets", of this leaflet. It is important that you read and understand the information about this serious reaction.

Other Side-effects

The most serious side-effects include:

- reduced red blood cell count (anaemia).
- reduced white blood cell count (neutropenia).

The frequency and severity of anaemia and neutropenia are greater in patients with advanced HIV disease, or in patients who start taking TRIZIVIR in later stages of HIV disease.

While you are taking TRIZIVIR, it is very important that your doctor keeps a close check on your health and takes blood samples to monitor levels of red and white blood cells. If you develop anaemia or neutropenia, your doctor may reduce or stop the dose of TRIZIVIR, or recommend standard treatment for these conditions.

On very rare occasions serious skin reactions have been reported.

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

Common side-effects associated with TRIZIVIR treatment include:

- body odour, chills, swelling of lips and/or tongue, flu-like symptoms, fever, increased sensitivity to pain, back pain, enlarged glands, chest pain, weakness, weight loss, generally feeling unwell.
- widening of blood vessels, possibly leading to low blood pressure or feeling faint.
- constipation, diarrhoea, difficulty in swallowing, gas from stomach or bowel, bleeding gums or nose, blood in stools, mouth ulcers, heartburn, vomiting, loss or reduction in appetite, nausea.
- abdominal discomfort and pain.
- muscle aches or pains, muscle shaking or spasm or twitching, muscle disease.
- enlarged fatty liver, abnormal results of blood tests of liver function, inflammation of the pancreas.
- confusion, depression, nervousness, fainting, loss of mental clarity, dizziness, seizures, severe headache, sleeplessness, fatigue/tiredness.
- cough, sore throat, hayfever, sinus problems, hoarseness.
- acne, itchiness, skin rash, changes in nail, skin or mouth colour.
- ear, nose and throat infection,
- vision problems, hearing loss, sensitivity to light.
- passing too much urine, pain, difficulty or increased frequency of passing urine.
- reduction in all blood cells.
- increased bruising or bleeding.
- blood chemistry changes, with excess acidity of the blood.
- unusual feelings in any part of the body, such as numbness, burning, tingling or pins and needles.
- hair loss

Changes in the amounts of fatty substances and glucose in the blood have also been reported.

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

Do not be alarmed by this list of possible side-effects. It is a list of the most common side-effects from the active ingredients contained in TRIZIVIR tablets. You may not experience any of them.

The side-effects may depend on whether you take TRIZIVIR alone, or also have taken other antiretroviral medication(s). Less is known about possible side-effects of taking TRIZIVIR with other antiretrovirals.

Call your doctor IMMEDIATELY if you notice any of the following. The doctor will tell you whether you should stop taking TRIZIVIR tablets and what you should do:

- **Lactic Acidosis**
  Some people taking TRIZIVIR, or other medicines like it (NRTIs), develop a condition called lactic acidosis, together with an enlarged liver.
  Lactic acidosis is caused by a build-up of lactic acid in the body. It is rare; if it happens, it usually develops after a few months of treatment. It can be life-threatening, causing failure of internal organs.
  Lactic acidosis is more likely to develop in people who have liver disease, especially in women.
  Signs of lactic acidosis include:
  - deep, rapid, difficult breathing
  - drowsiness
  - numbness or weakness in the limbs
  - feeling sick (nausea), being sick (vomiting)
  - stomach pain.
- **Allergic (anaphylactic) reaction**
  The symptoms of an allergic (anaphylactic) reaction which may occur soon after starting TRIZIVIR include wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting.
- **Old infections may flare up**
  People with advanced HIV infection (AIDS) have weak immune systems, and are more likely to develop serious infections (opportunistic infections). When these people start treatment, they may find that old, hidden infections flare up, causing signs and symptoms of inflammation. These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight these infections.

Your body shape may change

Treatment with TRIZIVIR or other medicines that contain zidovudine may cause a loss of fat from legs, arms and face (lipoatrophy). Your doctor should monitor for signs of lipoatrophy. Tell your doctor if you notice any loss of fat from your legs, arms, and face. When these signs occur, your doctor will assess if TRIZIVIR should be stopped and your HIV treatment changed. If you stop taking TRIZIVIR, it may take several months to see any lost fat return. You may not regain all of your lost body fat.

Pancreatitis

If you have any of the following symptoms soon after starting to take your medicine, do not take any more TRIZIVIR tablets and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital:

- **severe stomach pain or cramps.**
- **nausea.**
- **vomiting.**

These side-effects may be due to a condition called pancreatitis.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

How do I store TRIZIVIR tablets?

Keep this medicine where young children cannot reach them such as a locked cupboard.

Keep TRIZIVIR tablets in a cool, dry place where it stays below 30°C.

Do not store the tablets, or any other medicine, in a bathroom or near a sink.

Do not leave them in the car or on window sills.

Keep your TRIZIVIR tablets in their pack until it is time to take them.

If your doctor tells you to stop taking TRIZIVIR tablets, or the tablets have passed their expiry date, return any unused or expired medicine to your pharmacist.

Product description

What TRIZIVIR tablets look like.

TRIZIVIR tablets are blue/green capsule shaped, film-coated tablets, stamped with "GX LL1". The tablets are available in a bottle pack, (fitted with a child resistant closure) or blister packs. Each pack contains 60 tablets.

Ingredients

TRIZIVIR contains the active ingredients abacavir (as the sulfate, 300mg), lamivudine (150 mg) and zidovudine (300 mg).

TRIZIVIR tablets also contain the following inactive ingredients:
microcrystalline cellulose (E460), sodium starch glycollate, magnesium stearate (E572), hypromellose (E464), titanium dioxide (E171), macrogol 400, indigo carmine CI73015 (E132) aluminium lake and iron oxide yellow CI77492 (E172).

Manufacturer

ViiV Healthcare Pty Ltd
Level 4, 436 Johnston Street
Abbotsford, Victoria, 3067
AUSTRALIA.

Further Information

This is not all the information that is available on TRIZIVIR tablets. If you have any more questions or are not sure about anything, ask your doctor or pharmacist.

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

This leaflet was prepared on 27 June 2017

The information provided applies only to TRIZIVIR tablets.

TRIZIVIR tablets, bottle: AUST R 78348

TRIZIVIR tablets, blister: AUST R 78349

Version 7.0