

TRIUMEQ

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.

Important safety information on TRIUMEQ hypersensitivity reaction is provided in the [full CMI](#). Read before using this medicine.

1. Why am I using TRIUMEQ?

TRIUMEQ contains three active ingredients dolutegravir, abacavir and lamivudine. TRIUMEQ is used to treat human immunodeficiency virus (HIV) infection, which can lead to Acquired Immune Deficiency Syndrome (AIDS) and other related illnesses (eg AIDS-related Complex or ARC).

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

2. What should I know before I use TRIUMEQ?

Do not use if you have ever had an allergic reaction to dolutegravir, abacavir and lamivudine or any of the ingredients listed at the end of the CMI.

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 use TRIUMEQ?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TRIUMEQ 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 TRIUMEQ?

- The normal dose for adults and adolescents is one combined tablet, once a day.
- TRIUMEQ tablets should be swallowed whole with water.
- TRIUMEQ tablets do not have to be taken with food.

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

5. What should I know while using TRIUMEQ?

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| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist |
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| | <p>you visit that you are using TRIUMEQ.</p> <ul style="list-style-type: none"> • If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. • For as long as you're taking TRIUMEQ, your doctor will arrange regular blood tests to check for side effects. • Keep in contact with your doctor, and don't stop taking TRIUMEQ without your doctor's advice |
| Things you should not do | <ul style="list-style-type: none"> • Do not stop using this medicine or lower the dosage without checking with your doctor. |
| Driving or using machines | <ul style="list-style-type: none"> • Don't drive or use machines unless you are sure you're not affected. |
| Looking after your medicine | <ul style="list-style-type: none"> • Keep your tablets in a cool dry place where the temperature stays below 30°C. |

- Keep your tablets in the bottle until it is time to take them.
- Do not store TRIUMEQ or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car.

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

6. Are there any side effects?

The most common side effects are fever, skin rash, feeling sick (nausea and or vomiting), stomach pain (abdominal pain), tiredness, headache and rash.

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.

PATIENTS TAKING TRIUMEQ, WHICH CONTAINS ABACAVIR, MAY DEVELOP A HYPERSENSITIVITY REACTION (SERIOUS ALLERGIC REACTION) WHICH CAN BE LIFE-THREATENING IF TREATMENT WITH TRIUMEQ IS CONTINUED. CONTACT YOUR DOCTOR IMMEDIATELY FOR ADVICE ON WHETHER YOU SHOULD STOP TAKING TRIUMEQ 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 TRIUMEQ TABLETS, NEVER TAKE TRIUMEQ, OR ANY OTHER MEDICINAL PRODUCT CONTAINING ABACAVIR (TRIUMEQ, TRIZIVIR & ZIAGEN) AGAIN AS YOU MAY DEVELOP A LIFE THREATENING REACTION WHICH CAN BE FATAL.

THERE IS AN ALERT CARD INCLUDED IN THE TRIUMEQ 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 [5. WHAT SHOULD I KNOW WHILE USING TRIUMEQ?](#) .

TRIUMEQ

Active ingredients: *dolutegravir (as sodium), abacavir (as sulfate) and lamivudine*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using TRIUMEQ?

TRIUMEQ contains the active ingredients dolutegravir, abacavir and lamivudine. Dolutegravir belongs to a group of anti-retroviral medicines called integrase inhibitors (INIs). Abacavir and lamivudine belong to a group of anti-retroviral medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs).

TRIUMEQ is used to treat Human Immunodeficiency Virus (HIV) infection in adults and children over 12 years old.

TRIUMEQ does not cure HIV infection; it reduces the amount of virus in your body, and keeps it at a low level. TRIUMEQ also increases the CD4 cell count in your blood. CD4 cells are a type of white blood cells that are important in helping your body to fight infection.

To control your HIV infection, and to stop your illness from getting worse, you must keep taking all your medicines, unless your doctor tells you to stop taking any.

2. What should I know before I use TRIUMEQ?

Warnings

Do not use TRIUMEQ if:

- you are allergic to abacavir, which is also included in medicines called KIVEXA, TRIZIVIR and ZIAGEN.
- you are allergic to the active ingredients dolutegravir or lamivudine, or any of the ingredients listed at the end of this leaflet.
- if you're taking another medicine called dofetilide, pilsicainide (to treat heart conditions) or fampridine (used in multiple sclerosis).
- if you have a serious liver disease TRIUMEQ may not be suitable for you.

Check with your doctor if you:

- have a kidney problem. You may need extra check-ups, including blood tests, while you're taking this medicine.
- have any other medical conditions.
- take any medicines for any other condition.
- have allergies to any other medicines, foods, preservatives or dyes.

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.

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

Taking dolutegravir (one of the components of TRIUMEQ) at the time of becoming pregnant, or during the first twelve weeks of pregnancy, may increase the risk of a type of birth defect, called neural tube defect, such as spina bifida (malformed spinal cord).

Your doctor can discuss with you the risks and benefits involved.

Abacavir and lamivudine belong to a group of anti-retroviral medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs). In babies and infants exposed to NRTIs during pregnancy or labour small temporary increases in blood levels of a substance called lactate have been observed. Additionally, there have been very rare reports of diseases that affect the nervous system such as a delayed development and seizures. Overall, in children whose mothers took NRTIs during pregnancy, the benefit from the reduced chance of being infected with HIV is likely to be greater than the risk of suffering from side effects.

Where possible, women who are HIV-positive should not breast feed. This is because HIV infection can be passed on to the baby in breast milk. If formula feeding is not possible, you should get advice from your doctor.

A small amount of the ingredients in TRIUMEQ can also pass into your breast-milk.

Symptoms of infection and inflammation

People with advanced HIV infection (AIDS) have weak immune systems and are more likely to develop serious infections (opportunistic infections). When they start treatment, the immune system becomes stronger, so the body starts to fight infections.

Symptoms of infection and inflammation may develop, caused by either:

- old, hidden infections flaring up again as the body fights them.
- the immune system attacking healthy body tissue (autoimmune disorders).

The symptoms of autoimmune disorders may develop many months after you start taking medicine to treat your HIV infection.

Symptoms may include:

- muscle weakness and/or muscle pain
- joint pain or swelling
- weakness beginning in the hands and feet and moving up towards the trunk of the body
- palpitations or tremor

- hyperactivity (excessive restlessness and movement).

If you get any symptoms of infection or if you notice any of the symptoms above tell your doctor immediately.

Don't take other medicines for the infection without your doctors' advice.

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 TRIUMEQ and affect how it works.

Do not take TRIUMEQ with these medicines:

- dofetilide or pilsicainide, to treat heart conditions
- fampridine, used in multiple sclerosis.

These medicines should not be used with TRIUMEQ:

- emtricitabine, to treat HIV infection
- sorbitol-containing medicines (usually liquids) used regularly.

Tell your doctor if you are taking:

- metformin, to treat diabetes
- medicines called antacids, to treat indigestion and heartburn. Do not take an antacid that contains aluminium, calcium or magnesium during the 6 hours before you take TRIUMEQ, or for at least 2 hours after you take it. These antacids, readily available over the

counter, will decrease the effectiveness of TRIUMEQ if taken at the same time as TRIUMEQ.

- calcium and iron supplements. Do not take a calcium or iron supplement during the 6 hours before you take TRIUMEQ, or for at least 2 hours after you take it. If you take food with your medicine you can take a calcium or iron supplement at the same time as TRIUMEQ.
- etravirine, efavirenz, fosamprenavir/ritonavir, nevirapine or tipranavir/ritonavir, to treat HIV infection
- rifampicin, to treat tuberculosis (TB) and other bacterial infections
- co-trimoxazole, an antibiotic used to treat *Pneumocystis jiroveci* pneumonia (often referred to as PCP) or toxoplasmosis
- phenytoin and phenobarbital, to treat epilepsy
- carbamazepine, to treat epilepsy and bipolar disorder
- St. John's wort, (*Hypericum perforatum*), a herbal remedy to treat depression.

If you are taking methadone, your doctor may need to adjust your methadone dose, as abacavir (one of the active substances in TRIUMEQ) increases the rate at which methadone leaves your body. This is unlikely to affect most methadone users.

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

4. How do I take TRIUMEQ?

How much to take

- The usual dose of TRIUMEQ in adults and in children over the age of 12 years weighing at least 40 kg is one combined tablet (50 mg dolutegravir, 600 mg abacavir, 300 mg lamivudine) taken once a day.
- If you weigh less than 40kg, you cannot take TRIUMEQ, because the dose of each component of this medicine cannot be adjusted to your weight. Your doctor might prescribe the components separately for you.
- Follow the instructions provided and use TRIUMEQ until your doctor tells you to stop.

When to take TRIUMEQ

- TRIUMEQ should be taken at the same time each day. This will help you remember when to take it.

How to take TRIUMEQ

- TRIUMEQ should be swallowed whole with water. TRIUMEQ tablets do not have to be taken with food.

If you forget to take TRIUMEQ

TRIUMEQ should be taken regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then continue as before.

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 TRIUMEQ

If you think that you have taken too much TRIUMEQ, 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 TRIUMEQ?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking TRIUMEQ.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

Keep all of your doctor's appointments so that your progress can be checked.

If you have stopped taking TRIUMEQ tablets 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 or have another illness. In some cases your doctor will ask you to restart TRIUMEQ tablets where medical care can be readily accessed by yourself or others.

Call your doctor straight away if you:

- Become pregnant while taking this medicine.

Things you should not do

- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- If you have hepatitis B infection, you should not stop TRIUMEQ tablets without instructions from your doctor, as you may have a recurrence of your hepatitis. This may occur due to you suddenly stopping lamivudine.

Fat loss or fat gain

Fat loss or fat gain has been observed with combined antiretroviral therapy. A causal relationship for this has not been established. Should any change in body shape be noticed, seek medical advice.

Hypersensitivity reaction

TRIUMEQ 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.

What are the symptoms?

- The most common symptoms are:
- fever (high temperature) and skin rash.

Other common symptoms are:

- nausea (feeling sick), vomiting (being sick), diarrhoea, abdominal (stomach) pain, severe tiredness, shortness of breath, cough, headache, muscle pain and discomfort.

Other less common symptoms can include:

- pains in the joints, swelling of the neck, serious breathing problems, sore throat
- occasionally, inflammation of the eye (conjunctivitis), mouth ulcers, low blood pressure, tingling or numbness of the hands or feet.

When do these reactions happen?

- Hypersensitivity reactions can start at any time during treatment with TRIUMEQ but are more likely during the first 6 weeks of treatment.

Contact your doctor immediately:

- if you get a skin rash, OR
- if you get symptoms from at least 2 of the following groups:
 - fever
 - shortness of breath, sore throat or cough
 - nausea or vomiting, diarrhoea or stomach pain
 - severe tiredness or achiness, or generally feeling ill.

Always carry your Alert Card while you are taking TRIUMEQ.

If you have stopped taking TRIUMEQ:

If you have stopped taking TRIUMEQ because of a hypersensitivity reaction, you must NEVER AGAIN take TRIUMEQ, or any other medicine containing abacavir (ZIAGEN, KIVEXA or TRIZIVIR). If you do, within hours, your blood pressure could fall dangerously low, which

could result in death. You should also never again take medicines containing dolutegravir.

Talk to your doctor before you start again. Your doctor will check whether your symptoms were related to a hypersensitivity reaction. If the doctor thinks they may have been, you will then be told never again to take TRIUMEQ, or any other medicine containing abacavir. You may also be told never again to take any other medicine containing dolutegravir. It is important that you follow this advice.

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

You will need regular blood tests

For as long as you're taking TRIUMEQ, your doctor will arrange regular blood tests to check for side effects.

Stay in regular contact with you doctor

TRIUMEQ 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 TRIUMEQ does not cure HIV infection, you may still develop other infections and illnesses linked to HIV infection. Keep in contact with your doctor, and don't stop taking TRIUMEQ without your doctor's advice.

Driving or using machines

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

TRIUMEQ may make you dizzy or other side effects that may make you less alert.

Don't drive or use machines unless you're not affected.

Looking after your medicine

- Store in the original package in order to protect from moisture. Keep the bottle tightly closed. Do not remove the desiccant.
- Keep your tablets in a cool dry place where the temperature stays below 30°C.
- Do not store TRIUMEQ or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.
- Keep it where young children cannot reach it. 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.

Less serious side effects

| Less serious side effects | What to do |
|--|---|
| <p>Very common side effects</p> <p>These may affect more than 1 in 10 people:</p> <p>Gastrointestinal:</p> <ul style="list-style-type: none">• diarrhoea• feeling sick (nausea) <p>Nervous system:</p> <ul style="list-style-type: none">• headache <p>Common side effects</p> <p>These may affect at least 1 in 10 people:</p> <p>Gastrointestinal:</p> <ul style="list-style-type: none">• diarrhoea | <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"> ● being sick (vomiting) ● stomach pains (abdominal pain) and bloating (abdominal distension) ● stomach (abdominal) discomfort ● wind (flatulence) ● indigestion (dyspepsia) ● gastro-oesophageal reflux disease ● loss of appetite <p>General:</p> <ul style="list-style-type: none"> ● weight gain ● feeling drowsy ● tiredness, lack of energy ● general feeling of being unwell <p>Musculoskeletal:</p> <ul style="list-style-type: none"> ● joint pain ● muscle pain and discomfort <p>Nervous system:</p> <ul style="list-style-type: none"> ● high temperature (fever) ● dizziness <p>Psychiatric:</p> | |

| Less serious side effects | What to do |
|--|-------------------|
| <ul style="list-style-type: none"> ● nightmares and abnormal dreams ● sleep disorder ● depression (feelings of deep sadness and unworthiness) ● anxiety <p>Skin related:</p> <ul style="list-style-type: none"> ● hair loss ● skin rash ● itching (pruritis) <p>From blood tests:</p> <ul style="list-style-type: none"> ● increase in triglycerides (type of fat) in the blood ● increase in glucose (sugar) in the blood <p>Uncommon side effects</p> <p>These may affect up to 1 in 100 people:</p> <p>General:</p> <ul style="list-style-type: none"> ● inflammation of liver (hepatitis) <p>Psychiatric:</p> <ul style="list-style-type: none"> ● suicidal thoughts and behaviours (mainly in patients who have had | |

| Less serious side effects | What to do |
|---|-------------------|
| <p>depression or mental health problems before)</p> <p>From blood tests:</p> <ul style="list-style-type: none"> ● a low red blood cell count (anaemia) or low white blood cell count (neutropenia) ● a decrease in the number of cells involved in blood clotting (thrombocytopenia) ● an increase in the level of liver enzymes <p>Rare side effects</p> <p>These may affect up to 1 in 1000 people:</p> <p>General:</p> <ul style="list-style-type: none"> ● inflammation of the pancreas (pancreatitis) ● liver failure (signs may be yellowing of the skin and the whites of the eyes or unusually dark urine) <p>Musculoskeletal:</p> <ul style="list-style-type: none"> ● breakdown of muscle tissue. | |

| Less serious side effects | What to do |
|---|-------------------|
| <p>From blood tests:</p> <ul style="list-style-type: none"> ● increase in an enzyme called amylase. <p>Very rare side effects</p> <p>These may affect up to 1 in 10,000 people:</p> <p>Nervous system:</p> <ul style="list-style-type: none"> ● tingling or numbness of the hands and feet (paraesthesiae) ● tingling, numbness or weakness of the arms and legs (peripheral neuropathy) <p>Skin related:</p> <ul style="list-style-type: none"> ● skin rash, which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (erythema multiforme) ● widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes | |

| Less serious side effects | What to do |
|--|-------------------|
| <p>and genitals (Stevens-Johnson syndrome), and a more severe form causing skin peeling in more than 30% of the body surface (toxic epidermal necrolysis).</p> <ul style="list-style-type: none"> ● inflammation of the pancreas (pancreatitis) <p>From blood tests:</p> <ul style="list-style-type: none"> ● failure of bone marrow to produce new red blood cells | |

Serious side effects

| Serious side effects | What to do |
|---|--|
| <p>Lactic Acidosis</p> <ul style="list-style-type: none"> ● Some people taking TRIUMEQ, 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 | <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>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.</p> <ul style="list-style-type: none"> ● Lactic acidosis is more likely to develop in people who have liver disease, especially in women. ● Signs of lactic acidosis include: <ul style="list-style-type: none"> ○ deep, rapid, difficult breathing ○ drowsiness ○ numbness or weakness in the limbs ○ feeling sick (nausea), being sick (vomiting) ○ stomach pain. | |

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 TRIUMEQ contains

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|---|---|
| Active ingredient (main ingredient) | 50 mg of dolutegravir (as dolutegravir sodium), 600 mg of abacavir (as abacavir sulfate) and 300 mg lamivudine as the active ingredients. |
| Other ingredients (inactive ingredients) | mannitol microcrystalline cellulose povidone sodium starch glycolate |

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| | magnesium stearate polyvinyl alcohol titanium dioxide macrogol 3350 talc iron oxide red iron oxide black |
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Do not take this medicine if you are allergic to any of these ingredients.

What TRIUMEQ looks like

TRIUMEQ tablets are purple, oval, biconvex film-coated tablets debossed with '572 Tr#' on one side.
(AUST R 218644)

TRIUMEQ tablets are available in bottles of 30 tablets with child-resistant closure.

Who distributes TRIUMEQ

ViiV Healthcare Pty Ltd
Level 4, 436 Johnston St,
Abbotsford, Victoria, 3067
Australia.

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