

ZIAGEN oral solution

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 using ZIAGEN oral solution?

ZIAGEN oral solution contains the active ingredient abacavir which belongs to a group of medicines called antiretrovirals. ZIAGEN is used together 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).

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

2. What should I know before I use ZIAGEN oral solution?

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

3. What if I am taking other medicines?

Some medicines may interfere with ZIAGEN oral solution 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 ZIAGEN oral solution?

- Follow the instructions provided and use ZIAGEN oral solution until your doctor tells you to stop.
- If you are giving ZIAGEN oral solution to a child, follow the doctor's instructions.

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

5. What should I know while using ZIAGEN oral solution?

Things you should do	<ul style="list-style-type: none">• Tell your doctor if, for any reason, you have not taken your medicine exactly as directed• Remind any doctor, dentist or pharmacist you visit that you are using ZIAGEN oral solution
Things you should not do	<ul style="list-style-type: none">• Do not give this medicine to anyone else, even if their symptoms seem similar to yours• Do not use ZIAGEN oral solution to treat any other complaints unless your doctor tells you to
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 ZIAGEN oral solution affects you
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C• Store in the original pack

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

6. Are there any side effects?

Side effects which have been reported include headache, nausea & vomiting, diarrhoea, fever/high temperature, fatigue/tiredness, anorexia/loss of appetite, rash, abdominal discomfort and pain, cough, ear, nose & throat infection, insomnia, muscular pain, reduced white blood cell count (neutropenia), pancreatitis, and changes in the immune system. Serious side effects include lactic acidosis, allergic reaction, flare up of old infections, and fat loss or gain.

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

THERE IS AN ALERT CARD INCLUDED IN THE ZIAGEN oral solution 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 USE ZIAGEN oral solution.

ZIAGEN oral solution

Active ingredient(s): *abacavir (as sulfate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZIAGEN oral solution. **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 ZIAGEN oral solution.**

Where to find information in this leaflet:

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

1. Why am I using ZIAGEN oral solution?

ZIAGEN oral solution contains the active ingredient abacavir which belongs to a group of medicines called antiretrovirals.

ZIAGEN oral solution is used together 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).

ZIAGEN oral solution does not cure AIDS or kill the HIV virus, but prevents further damage to the immune system by stopping the production of new viruses.

You can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. You will still be able to pass on the HIV virus by sexual activity or by contamination with infected blood. You should still use proper precautions to prevent this.

Discuss with your doctor the precautions needed to avoid infecting other people.

While taking ZIAGEN oral solution 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 who is looking after you.

2. What should I know before I use ZIAGEN oral solution?

Warnings

Do not use ZIAGEN oral solution if:

- you are allergic to abacavir, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine
 - 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 ZIAGEN oral solution treatment
 - **YOU MUST NOT TAKE ZIAGEN oral solution OR ANY OTHER ABACAVIR CONTAINING PRODUCTS (KIVEXA, TRIZIVIR), AGAIN**

Special warning

ZIAGEN oral solution 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 ZIAGEN oral solution. If your doctor is not available, you must urgently seek other medical advice (e.g. the Emergency Department 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 with ZIAGEN oral solution. However, they usually occur in the first six weeks of treatment and get worse with continued treatment.

If you have had this serious reaction to ZIAGEN oral solution, NEVER take ZIAGEN, or any other abacavir containing products (KIVEXA, TRIUMEQ), 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 ZIAGEN oral solution 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 ZIAGEN oral solution was re-started in patients who had no symptoms of hypersensitivity before stopping.

If you have stopped taking ZIAGEN oral solution 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 ZIAGEN oral solution or any other abacavir containing products (KIVEXA, TRIUMEQ) again. It is important that you follow this advice.

If you are hypersensitive to ZIAGEN oral solution you should return all of your unused medicine to your pharmacist for proper disposal.

Check with your doctor if you:

- have any other medical conditions/illness such as:
 - liver problems, e.g. jaundice, hepatitis, virus affecting the liver, enlarged liver or liver scarring (cirrhosis) or if you have any risk factors for liver problems

- hereditary fructose intolerance
 - this medicine contains the sweetener sorbitol, which occasionally may cause stomach pain and diarrhoea. Medicines containing sorbitol should not be taken if you have a hereditary fructose intolerance
- 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.

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 ZIAGEN oral solution and affect how it works.

Tell your doctor if you are taking riociguat (a medicine used to treat high blood pressure in the blood vessels (the pulmonary arteries) that carry blood from the heart to the lungs) your doctor may need to reduce your riociguat dose, as abacavir (the active substance in ZIAGEN oral solution) may increase riociguat blood levels.

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

4. How do I use ZIAGEN oral solution?

How much to take

- the normal dose in adults and children weighing at least 25 kg is 15 mL (300 mg) twice a day.
- your doctor may prescribe a different dose.
- follow the instructions provided and use ZIAGEN oral solution until your doctor tells you to stop.
- if you are giving ZIAGEN oral solution to a child, follow the doctor's instructions.

How to take ZIAGEN oral solution

To measure your dose of ZIAGEN oral solution accurately use the dosing syringe supplied as follows:

1. Remove the plastic wrap from the syringe/adapter
2. Remove the bottle cap

3. Remove the plastic adapter from the syringe
4. Push the plastic adapter into the neck of the bottle, while holding the bottle firmly
5. Insert the syringe firmly into the adapter
6. Turn the bottle upside down
7. Pull out syringe plunger until the correct amount is withdrawn
8. Turn the bottle the correct way up and remove the syringe from the adapter
9. Replace and tighten the bottle cap
10. Administer the dose into the mouth by placing the tip of the syringe against the inside of the cheek. Slowly depress the plunger, allowing time to swallow. Forceful squirting to the back of the throat may cause choking

After use the syringe and adapter must not be left in the bottle. They should be washed thoroughly in clean water.

When to use ZIAGEN oral solution

- because your medicine helps to control your condition, but does not cure it, you will need to use the oral solution every day. Do not stop using ZIAGEN oral solution or change the dose without first talking to your doctor.

If you forget to use ZIAGEN oral solution

ZIAGEN oral solution should be used regularly at the same time each day. If you miss your dose at the usual time, and 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 you missed.

If you use too much

If you think that you have used too much ZIAGEN, 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.

If you have stopped using ZIAGEN oral solution

If you have stopped taking ZIAGEN oral solution 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 ZIAGEN oral solution where medical care can be readily accessed by yourself or others. If your doctor thinks that there is a possibility that your symptoms were related to a

hypersensitivity reaction, you may be told never to take ZIAGEN oral solution again.

5. What should I know while using ZIAGEN oral solution?

Things you should do

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Remind any doctor, dentist or pharmacist you visit that you are using ZIAGEN oral solution.

Things you should not do

- **do not give this medicine to anyone else, even if their symptoms seem similar to yours**
- **do not use ZIAGEN oral solution 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 ZIAGEN oral solution affects you.

Looking after your medicine

- store below 25°C

- store in the original pack

Follow the instructions on the carton on how to take care of your medicine properly.

Keep your ZIAGEN oral solution in the bottle with the cap tightly closed until you need to take it. Shake the bottle before use.

Store it in a cool dry place 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.

Hypersensitivity Reaction

ZIAGEN oral solution 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. This is described in the section "Special warning" under [2. What should I know before I use ZIAGEN oral solution?](#) of this leaflet.

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>Nervous system disorders</p> <ul style="list-style-type: none">• headache• insomnia <p>Gastrointestinal disorders</p> <ul style="list-style-type: none">• nausea, vomiting• diarrhoea• anorexia/loss of appetite• abdominal discomfort and pain <p>General disorders</p> <ul style="list-style-type: none">• fever/high temperature• fatigue/tiredness <p>Skin and subcutaneous tissue disorders</p> <ul style="list-style-type: none">• rash	<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
<p>Respiratory disorders</p> <ul style="list-style-type: none"> • cough <p>Infections and infestations</p> <ul style="list-style-type: none"> • ear, nose & throat infection <p>Musculoskeletal and connective tissue disorders</p> <ul style="list-style-type: none"> • muscular pain <p>Blood and lymphatic system disorders</p> <ul style="list-style-type: none"> • reduced white blood cell count (neutropenia) <p>Endocrine disorders</p> <ul style="list-style-type: none"> • pancreatitis <p>Immune system disorders</p> <ul style="list-style-type: none"> • changes in your immune system <p>A condition called Immune Reconstitution Syndrome can happen when you start taking HIV medicines. Your immune system may get stronger and could begin to fight infections</p>	

Less serious side effects	What to do
<p>that have been hidden in your body such as pneumonia, herpes virus or tuberculosis. Tell your doctor if you develop new symptoms after starting your HIV medicines.</p> <p>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. If you become concerned about any new symptoms, or any changes in your health after starting HIV treatment, please</p>	

Less serious side effects	What to do
<p>discuss with your doctor immediately.</p> <p>On very rare occasions serious skin reactions have been reported.</p>	

Serious side effects

Serious side effects	What to do
<p>Metabolism and nutrition disorders</p> <ul style="list-style-type: none"> • lactic acidosis <p>Some people taking ZIAGEN oral solution, or other medicines like it (NRTIs), develop a condition called lactic acidosis, together with an enlarged liver.</p> <p>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,</p>	<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>causing failure of internal organs.</p> <p>Lactic acidosis is more likely to develop in people who have liver disease, especially in women.</p> <p>Signs of lactic acidosis include:</p> <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 ● fat loss or fat gain <p>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.</p>	

Serious side effects	What to do
<p>Immune system disorders</p> <ul style="list-style-type: none"> • allergic (anaphylactic) reaction <p>The symptoms of an allergic (anaphylactic) reaction which may occur soon after starting ZIAGEN oral solution include wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting.</p> <p>Infections and infestations</p> <ul style="list-style-type: none"> • old infections may flare up <p>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.</p>	

Serious side effects	What to do
These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight these infections.	

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 ZIAGEN oral solution contains

Active ingredient (main ingredient)	abacavir (as sulfate)
Other ingredients (inactive ingredients)	sorbitol solution (70%) saccharin sodium sodium citrate dihydrate citric acid methyl hydroxybenzoate propyl hydroxybenzoate propylene glycol artificial strawberry artificial banana flavour purified water

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

What ZIAGEN oral solution looks like

ZIAGEN oral solution is a clear to yellowish solution which may turn into a brown colour over time with strawberry/banana flavour. Each 1 mL of solution contains 20 mg of abacavir as the sulfate salt (AUST R 66879).

ZIAGEN oral solution is supplied in a white polyethylene bottle with a polypropylene or polyethylene child-resistant closure. The bottle contains 240 mL of solution for oral use only and is packed in a carton.

The pack includes an oral dosing syringe and syringe-adaptor.

ZIAGEN is also available as tablets (300 mg abacavir).

Who distributes ZIAGEN oral solution

ViiV Healthcare Pty Ltd

Level 4, 436 Johnston Street,

Abbotsford, Victoria, 3067

Phone: 1800 499 226

www.viivhealthcare.com.au

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