

ZIAGEN oral solution

abacavir (as sulfate)

Consumer Medicine Information

PATIENTS TAKING ZIAGEN, 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 NEVER TAKE ZIAGEN, OR ANY OTHER MEDICINAL PRODUCT CONTAINING ABACAVIR (KIVEXA, TRIZIVIR and TRIUMEQ) AGAIN AS YOU MAY DEVELOP A LIFE THREATENING REACTION WHICH CAN BE FATAL.

THERE IS AN ALERT CARD INCLUDED IN THE ZIAGEN 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 ZIAGEN.

What is in this leaflet?

Please read this leaflet carefully before you start ZIAGEN oral solution.

This leaflet answers some common questions about ZIAGEN oral solution. 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 benefits and risks. Your doctor has weighed the expected benefits of you taking ZIAGEN 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 oral solution.

You may need to read it again.

HYPERSENSITIVITY REACTION

ZIAGEN contains abacavir (which is also an active ingredient in KIVEXA, TRIZIVIR and TRIUMEQ).

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. It is important you read the information on this reaction in the section "Special Warning" under "Before you take ZIAGEN oral solution", of this leaflet. There is also an Alert Card included in the ZIAGEN pack, to remind you and medical staff about ZIAGEN 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 ZIAGEN. 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 ZIAGEN, NEVER take ZIAGEN or any other abacavir containing products (KIVEXA, TRIZIVIR and TRIUMEQ), again as WITHIN HOURS you may experience a life-threatening lowering of your blood pressure leading to possible death.

What ZIAGEN oral solution is used for

ZIAGEN oral solution contains 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 (eg AIDS-related Complex or ARC).

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

While taking ZIAGEN 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.

ZIAGEN oral solution is not addictive.

Before you take ZIAGEN oral solution

Do not take if:

You must not take ZIAGEN oral solution if:

- you have ever had an allergic reaction to abacavir or any of the other ingredients listed toward the end of this leaflet.

Special warning

ZIAGEN 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. 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 with ZIAGEN. 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, NEVER take ZIAGEN, or any other abacavir containing products (KIVEXA, TRIZIVIR and 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 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 was re-started in patients who had no symptoms of hypersensitivity before stopping.

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

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

You must not take ZIAGEN oral solution 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 treatment. **YOU MUST NOT TAKE ZIAGEN OR ANY OTHER ABACAVIR CONTAINING PRODUCTS (KIVEXA, TRIZIVIR and TRIUMEQ), AGAIN.**
- you are pregnant, think you may be pregnant or breastfeeding, unless your doctor tells you to.
- the expiry date (EXP.) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

Tell your doctor if:

You must tell your doctor if:

- you are allergic to foods, dyes, preservatives or any other medicines.
- you had a previous allergic reaction to ZIAGEN (abacavir) containing products.
- 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.
- you have any other illness.
- you are taking any other medicines, including medicines you buy without a prescription.
- 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) may increase riociguat blood levels.

How do I take ZIAGEN oral solution?

How much to take

Take ZIAGEN oral solution as directed by your doctor or pharmacist. The normal dose in adults, adolescents and children weighing at least 25 kg is 15 mL (300 mg) twice a day. Your doctor may prescribe a different dosage.

If you are giving Ziagen oral solution to a child, follow the doctor's instructions.

How to take it

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. Push the plastic adapter into the neck of the bottle, while holding the bottle firmly.
4. Remove the plastic adapter from the syringe.
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.

How long to take it for

Because your medicine helps to control your condition, but does not cure it, you will need to take the oral solution every day. Do not stop taking ZIAGEN oral solution or change the dose 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 much ZIAGEN oral solution immediately telephone your doctor or Poisons Information Centre (In Australia telephone 131126. In New Zealand telephone 0800 POISON). 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 ZIAGEN oral solution

Things you must 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.

If you forget to take it

If you have forgotten to take a dose of your medicine 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 that you missed.

If you have stopped taking it

If you have stopped taking ZIAGEN 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 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 again.

Things you must 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.

Things to be careful of

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

What are the side effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions while taking ZIAGEN oral solution, even if the problem is not listed in this leaflet.

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

Hypersensitivity Reaction

ZIAGEN 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 "Before you take ZIAGEN oral solution", of this leaflet.

It is important that you read and understand the information about this serious reaction.

Other Side-effects

The most commonly reported side effects include:

- Headache.
- Nausea & vomiting.
- Diarrhoea.
- Fever/high temperature
- Fatigue/tiredness.
- Anorexia/loss of appetite.
- Rash

Other side effects that have been reported include:

- Abdominal discomfort and pain.
- Cough.
- Ear, nose & throat infection.
- Insomnia.
- Muscular pain.
- Reduced white blood cell count (neutropenia).
- Pancreatitis.
- Changes in the amounts of fatty substances and glucose in the blood.

Changes in your immune system.

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 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.

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.

On very rare occasions serious skin reactions have been reported.

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

- **Lactic Acidosis**

Some people taking ZIAGEN, 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 ZIAGEN 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.

This is not a complete list of all possible side effects. Others may

occur in some people and there may be some side effects not yet known.

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

After using ZIAGEN oral solution?

Storage

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

Keep ZIAGEN oral solution in a cool, dry place where it stays below 30°C.

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

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

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

If your doctor tells you to stop taking ZIAGEN oral solution, or the oral solution has passed its expiry date, return any unused or expired medicine to your pharmacist.

Product description

What ZIAGEN oral solution looks like.

The 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.

ZIAGEN oral solution is supplied in a white polyethylene bottle with a cap. 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-adapter.

Ingredients

ZIAGEN oral solution contains 20 mg per mL of abacavir as the sulfate salt. Your oral solution also contains the following inactive ingredients:

Sorbitol (34%), saccharin sodium, sodium citrate, anhydrous citric acid, methyl hydroxybenzoate, propyl hydroxybenzoate, propylene glycol, artificial strawberry and banana flavour and purified water.

Sponsor Details

GlaxoSmithKline NZ Ltd

Private Bag 106600

Downtown

Auckland 1143

NEW ZEALAND

Ph: (09) 367 2900

Fax (09) 367 2910

Where to go for further information

ZIAGEN is also available as tablets (300 mg abacavir)

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 the individual advice you need. You may also be able to find out more information about your disease from books, for example in public libraries.

Counselling is also available from your local AIDS council.

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The information provided applies only to ZIAGEN oral solution.

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