

ZIAGEN(R) tablets

abacavir (as sulfate)

Consumer Medicine Information

If you have had a hypersensitivity (allergic) reaction to ZIAGEN, NEVER take ZIAGEN, or any other medicine containing abacavir (Trizivir(R) Kivexa(R)) again as you may develop a life threatening reaction, which can be fatal. See more details under Side Effects.

What is in this leaflet?

Please read this leaflet carefully before you start ZIAGEN tablets.

This leaflet answers some common questions about ZIAGEN 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 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 tablets.

You may need to read it again.

HYPERSENSITIVITY REACTION

Patients taking ZIAGEN may develop a hypersensitivity reaction (serious allergic reaction) which can be life threatening if you continue to take ZIAGEN. It is important you read the information on this reaction in the section "Special Warning" under "Before you take ZIAGEN tablets", 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 medicine containing abacavir (Trizivir, Kivexa) again as WITHIN HOURS you may experience a life-threatening lowering of your blood pressure leading to possible death.

What ZIAGEN tablets are used for

ZIAGEN tablets contain 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.

ZIAGEN does not reduce the risk of passing the 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 still use proper precautions to prevent this.

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 tablets are not addictive.

Before you take ZIAGEN tablets

Do not take if:

You must not take ZIAGEN tablets 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

Hypersensitivity reaction (serious allergic reaction): About 5 in every 100 patients who are treated with ZIAGEN develop a hypersensitivity reaction to the active ingredient abacavir.

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 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 medicine containing abacavir (Trizivir,

Kivexa) 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 medicine containing abacavir (Trizivir, Kivexa) 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 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 ZIAGEN treatment. **YOU MUST NOT TAKE ZIAGEN, OR ANY OTHER MEDICINE CONTAINING ABACAVIR (TRIZIVIR, KIVEXA) AGAIN.**
- * you are pregnant, think you may be pregnant or are 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.

How do I take ZIAGEN tablets?

How much to take

Take ZIAGEN tablets as directed by your doctor or pharmacist. The usual daily dose of Ziagen in adults and adolescents over 12 years of age is 600 mg. This can be taken either as 1 x 300 mg tablet twice a day, approximately 12 hours apart or 2 x 300 mg tablets once a day. Your doctor may prescribe a different dosage.

If you are giving ZIAGEN tablets to a child, follow the doctor's instructions. ZIAGEN oral solution is also available for younger patients, or those who cannot swallow tablets.

How to take them

ZIAGEN tablets should be swallowed whole, with water or another drink. Ziagen does not need to be taken with food.

How long to take them for

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 ZIAGEN tablets 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 many ZIAGEN tablets, 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 tablets

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 them

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 them

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 tablets to treat any other complaints unless your doctor tells you to.

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 tablets, even if the problem is not listed in this leaflet.

Like all medicines, ZIAGEN tablets 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

An important side-effect called a hypersensitivity reaction (serious allergic reaction) has been reported in about five in every hundred patients who have been treated with ZIAGEN. This is described in the section "Special warning" under "Before you take ZIAGEN tablets", 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)

Changes in fat distribution have been reported in association with combination antiretroviral therapy. These may include:

- * Loss of body fat from areas such as legs, arms and face
- * Increased fat appearing in areas such as abdomen (belly) and other internal organs, breasts and the back of the neck

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 tablets and what you should do:

*** Lactic Acidosis**

If you become very sick, with fast breathing you may have a condition known as "lactic acidosis". The fast breathing is due to high acid levels in the blood. This can be life-threatening. This illness occurs more often in women than men.

*** 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.

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.

How do I store ZIAGEN tablets?

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

Keep ZIAGEN tablets in a cool, dry place where it stays below 30 degrees 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 ZIAGEN tablets in the blister pack until you take them.

If your doctor tells you to stop taking ZIAGEN tablets, or the tablets have passed their expiry date, return any

unused or expired medicine to your pharmacist.

Product description

What ZIAGEN tablets look like

The tablets are yellow, film-coated, capsule-shaped tablets engraved "GX 623" on one face.

ZIAGEN tablets are supplied in a white polyvinyl chloride (PVC)/aluminium foil blister pack. The blister pack is in a carton containing 60 tablets.

Ingredients

ZIAGEN tablets contain 300 mg of abacavir as the sulfate salt. Your tablets also contain the following inactive ingredients:

Microcrystalline cellulose, sodium starch glycollate, magnesium stearate, colloidal anhydrous silica, glycerol triacetate, hypromellose, titanium dioxide, polysorbate 80 and iron oxide yellow (E172).

Supplier

Your ZIAGEN tablets are supplied by:

GlaxoSmithKline Australia Ltd Ltd
1061 Mountain Highway
Boronia, Victoria, 3155
AUSTRALIA.

or

GlaxoSmithKline Ltd
Auckland, NEW ZEALAND

Where to go for further information

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.

This leaflet was prepared on 24th September 2008

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