

ZIAGEN[®] Tablets

abacavir (as sulphate) 300mg

Consumer Medicine Information

If you have had a hypersensitivity (allergic) reaction to Ziagen, NEVER take Ziagen again as you may develop a life threatening reaction which has caused death. See more details under Side Effects.

What is in this leaflet?

Please read this leaflet carefully before you start taking 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. Sometimes new risks are found even when a medicine has been used for many years. Your doctor has weighed the risks of you taking Ziagen against the expected benefits it will 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 you have had this reaction to Ziagen, **NEVER** take Ziagen again as **WITHIN HOURS** you may experience a life-threatening lowering of your blood pressure or 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 and interrupting the reproduction of the virus.

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.

Ask your doctor if you have any questions about why Ziagen tablets have been prescribed for you.

Before you take Ziagen tablets

When you must not take them

- This medicine must not be taken if you are allergic to the active substance abacavir or any of the other ingredients found in Ziagen. If you are not sure please consult your doctor.

Special warning

Hypersensitivity reaction (serious allergic reaction): About 4 in every 100 patients, who are treated with Ziagen, develop a hypersensitivity reaction to the active ingredient abacavir. 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. Other symptoms may include joint or muscle pain, swelling of the neck, headache. Occasionally inflammation of the eye (conjunctivitis), ulcers in the mouth or low blood pressure may occur. The symptoms of this allergic reaction usually occur in the first six weeks of treatment with Ziagen, and get worse with continued treatment.

If you have had this serious reaction to Ziagen, **NEVER** take Ziagen again as **within hours** you may experience a life-threatening lowering of your blood pressure or death.

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

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 AGAIN.**

- Do not take ZIAGEN tablets if you are pregnant, think you may be pregnant or breastfeeding, unless your doctor says you should.

Your doctor will discuss the risks and benefits of using Ziagen tablets if you are pregnant or breastfeeding.

- Do not take Ziagen if you have liver impairment/liver disease
- Do not take Ziagen tablets after the expiry or “use by” date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

- Do not take Ziagen tablets if the packaging is torn or shows signs of tampering.

If you're not sure whether you should be taking Ziagen tablets, talk to your doctor.

Before you start taking Ziagen

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, 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.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking Ziagen tablets with other medicines.

How to take ZIAGEN tablets

Your doctor will tell you how many Ziagen tablets to take and how often to take them. You will also find this information on the label of your medicine.

Do not take extra tablets. Do not take the tablets more often than you have been told.

How much to take

The normal adult dose is one 300 mg tablet twice 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

Take your Ziagen tablets as your doctor has advised you. Ziagen tablets should be swallowed whole with water or another drink. Ziagen does not have to be taken with food.

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.

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 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 (03 474 7000) or go to accident and emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning. This may need urgent medical attention.

Keep telephone numbers for these places handy.

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 or pharmacist that you are taking Ziagen tablets if you are about to be started on any other medicines.

Tell your doctor if you become pregnant or think you may be 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.

Things you must not do

Do not stop taking Ziagen tablets, or change the dose without first checking with your doctor.

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 says to.

Do not take Ziagen tablets again if you have had an allergic reaction to them.

Side-Effects

Check with your doctor as soon as possible if you have any problems while taking Ziagen tablets, even if you do not think the problems are connected with the medicine or are 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
A hypersensitivity reaction (serious allergic reaction) has been reported in about 4 in every 100 patients who have been treated with Ziagen. This is described in the section “Special Warnings” under “Before you take your Ziagen tablets”, of this leaflet. It is important that you read and understand the information about this serious reaction.

Other Side-effects associated with Ziagen hypersensitivity include:

- Headache
- Nausea & vomiting
- Diarrhoea
- Fever/high temperature
- Fatigue/tiredness
- Anorexia/loss of appetite
- Rash, hives
- General feeling of unwellness
- Aching muscles

If you have any of the above symptoms soon after starting to take your medicine, **DO NOT TAKE ANY MORE ZIAGEN TABLETS** and tell your doctor **IMMEDIATELY** or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects. If you have them, you may have a serious allergic reaction. You may need urgent medical attention or hospitalisation.

Lactic Acidosis
Ziagen belongs to a class of antiretrovirals called nucleoside analogues. There have been reports of a serious condition called “lactic acidosis” from patients taking these medicines. If you are on medication for HIV and become very sick, with fast breathing, stop taking ZIAGEN tablets and consult your doctor immediately. You may have this condition. The fast breathing is due to high acid levels in the blood. Your liver may not be working properly and gets big and fatty. This can be life threatening. This illness

occurs more often in women than men.

Redistribution, accumulation or loss of body fat may occur in patients receiving combination antiretroviral therapy. Contact your doctor if you notice changes in body fat.

Other side effects that have been reported include:

- Abdominal discomfort and pain
- Mouth ulcers
- Cough
- Ear, nose & throat infection
- Insomnia
- Joint pain
- Reduced white blood cell count (neutropenia), making you feel tired, dizzy
- Fever, chills
- Shortness of breath/difficulty breathing
- Swollen glands in the neck, groin and armpits
- Conjunctivitis
- Liver and kidney problems

Ask your doctor or pharmacist to answer any questions you may have.

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

Some people may get other side effects while taking Ziagen tablets. If you are concerned, talk to your doctor or pharmacist.

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

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

After taking Ziagen tablets

Storage

Keep the tablets where children cannot reach them.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store them.

Keep Ziagen 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.

Heat and dampness can destroy some medicines.

Keep your Ziagen tablets in the blister pack until you take them.

If you take Ziagen tablets out of their pack they may not keep well.

Disposal

If your doctor tells you to stop taking Ziagen tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What Ziagen tablets look like

The scored film coated tablets are yellow, biconvex, and capsule shaped. They are engraved with "GX 623" on both sides.

Ziagen tablets are supplied in a white polyvinyl chloride (PVC)/aluminium foil blister pack. The blister pack contains 60 tablets for oral use only and is in a carton.

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).

Ziagen tablets do not contain gluten.

Manufacturer

Your Ziagen tablets are supplied by:

GlaxoSmithKline NZ
AMP Centre
Cnr Albert & Customs Streets
Private Bag 106600
Downtown Auckland
New Zealand

Further Information

This is not all the information that is available on Ziagen 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 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.

Do not throw this leaflet away.
You may need to read it again.

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The information provided applies only to: Ziagen® tablets.

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