

ZIAGEN TABLET / ORAL SOLUTION

Abacavir sulfate (300mg, 20mg/mL)

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What Ziagen is used for

Ziagen contains the active ingredient abacavir sulfate. This belongs to a group of anti-retroviral medicines called *nucleoside analogue reverse transcriptase inhibitors (NRTIs)*, which are used to treat Human Immunodeficiency Virus (HIV) infection.

How Ziagen works

Ziagen does not cure HIV infection; it reduces the amount of virus in your body, and keeps it at a low level. It 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. Not everyone responds to treatment with Ziagen in the same way. Your doctor will monitor the effectiveness of your treatment.

Before you use Ziagen

- When you must not use it

Do not take Ziagen:

- if you are allergic (hypersensitive) to abacavir (or any other medicine containing abacavir), or any other ingredients of Ziagen.

Carefully read all the information about hypersensitivity reactions in section 'Side Effects'.

If you think this applies to you, don't take Ziagen until you have checked with your doctor.

- Before you start to use it

Before you take Ziagen your doctor needs to know:

- if you have ever had liver disease, including hepatitis B or C

Talk to your doctor if this apply to you. You may need extra check-ups, including blood tests, while you're taking your medicine.

Pregnancy:

If you are pregnant, or think you could be, or if you are planning to become pregnant, don't take Ziagen without checking with your doctor. Your doctor will weigh up the benefit to you against the risk to your baby of taking Ziagen while you're pregnant and advise you if you should continue taking Ziagen. 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.

Breast-feeding:

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 Ziagen can also pass into your breast milk.

Talk to your doctor immediately if you're breast-feeding or thinking about breast-feeding.

- Taking other medicines

Tell your doctor or pharmacist if you're taking any other medicines, if you've taken any recently, or if you start taking new ones. This includes medicines bought without a prescription.

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

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) may increase riociguat blood levels.

How to use ZIAGEN

- How much to use

The usual dose of Ziagen in adults and in children weighing at least 25 kg is 600 mg a day. This can be taken as 300 mg (one tablet) twice a day, or 600 mg (two tablets) once a day, as advised by your doctor.

The usual dose of Ziagen in children weighing at least 20 kg and less than 25 kg is 450 mg a day. This can be taken as 150 mg (half a tablet) in the morning and 300 mg (one whole tablet) in the evening, or 450 mg (one and a half tablets) once a day as advised by your doctor.

The usual dose of Ziagen in children weighing at least 14 kg and less than 20 kg is 300 mg a day. This can be taken as 150 mg (half a tablet) twice a day, or 300 mg (one whole tablet) once a day, as advised by your doctor.

Ziagen is also available as an oral solution (20 mg/ml) and may be prescribed by your doctor if you need a lower dose than usual or if you cannot take tablets.

- When to use it

Always take Ziagen exactly as your doctor has told you and take great care

not to miss any doses if at all possible. Please check with your doctor or pharmacist if you are not sure.

- How long to use it

Stay in regular contact with your doctor. Ziagen helps to control your condition. You need to keep taking it every day to stop your illness getting worse. You may still develop other infections and illnesses linked to HIV infection. Keep in touch with your doctor, and don't stop taking Ziagen without your doctor's advice.

- If you forget to use it

Don't take a double dose to make up for a missed dose. Just take it as soon as you remember. If you are not sure what to do, ask your doctor or pharmacist.

- If you use too much (overdose)

If you take too many tablets or too much oral solution of Ziagen, contact your doctor or pharmacist, or your nearest hospital emergency department for advice. If possible, show them the Ziagen pack.

While you are using it

- Things you must do

Ziagen can be taken with or without food.

The tablet should be swallowed without crushing.

If you cannot swallow the tablet(s), Ziagen is available as an oral solution: Please talk to your doctor.

Alternatively, you may crush and add them to a small amount of semi-solid food or drink, and take all the dose immediately.

Abacavir hypersensitivity reaction

Carefully read all the information about hypersensitivity reactions in Section 'Side Effect' of this leaflet. If you have stopped taking Ziagen for any reason, especially because you think you are having side effects, or because you have other illness: 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 Ziagen, or any other medicine containing abacavir. It is important that you follow this advice. The Ziagen pack includes an Alert Card, to remind you and medical staff about hypersensitivity reactions. Detach this card and keep it with you at all times.

If your doctor advises that you can start taking Ziagen again, you may be asked to take your first doses in a place where you will have ready access to medical care if you need it.

- Things you must not do

If you have hepatitis B infection, don't stop Ziagen without your doctor's advice, as your hepatitis may come back.

- Things to be careful of

Ziagen can cause serious side effects. You must look out for certain symptoms while you are taking Ziagen, to reduce the risk of any problems.

Hypersensitivity reactions

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. Carefully read all the information about hypersensitivity reactions in Section 'Side Effect' of this leaflet.

Heart disease

Some studies have shown a small increase in the risk of having a heart attack in people taking abacavir, the active ingredient of Ziagen. Other studies have not shown any increased risk of heart attack in patients using abacavir. Tell your doctor if you have heart problems, if you smoke, or have other illnesses that may increase your

risk of heart disease such as high blood pressure, or diabetes. Don't stop taking Ziagen unless your doctor advises you to do so.

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. If you get any symptoms of infection while you're taking Ziagen: Tell your doctor immediately. Don't take other medicines for the infection without your doctor's advice.

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
- nausea, vomiting
- stomach pain

During your treatment, your doctor will monitor you for signs of lactic acidosis. If you have any of the symptoms listed above or any other symptoms that worry you: See your doctor as soon as possible.

Oral Solution:

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.

Protect other people

HIV infection is spread by sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles). You can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor the precautions needed to avoid infecting other people.

Side Effects

Like all medicines, Ziagen can have side effects, although not everybody gets them.

When you're being treated for HIV, it can be hard to tell whether a symptom is a side effect of Ziagen or other medicines you are taking, or an effect of the HIV disease itself. So it is very important to talk to your doctor about any changes in your health.

Hypersensitivity reactions

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.

Contact your doctor immediately:

1 if you get a skin rash, OR
2 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.

Common side effects

- headache
- feeling sick (nausea)
- hypersensitivity reaction (please refer to 'Hypersensitivity reactions' section above)
- being sick (vomiting)
- diarrhoea
- loss of appetite
- tiredness, lack of energy
- high temperature (fever)
- skin rash

Rare side effects

- lactic acidosis
- inflammation of the pancreas

Very rare side effects

- 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*)
- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens–Johnson syndrome*), and a more severe form causing skin peeling in more than 30% of the body surface (toxic epidermal necrolysis).

If you notice any of these symptoms contact a doctor urgently.

If you get side effects, tell your doctor or pharmacist if any of the side effects become severe or troublesome, or if you notice any side effects not listed in this leaflet.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Ziagen

- Storage

- Keep Ziagen out of reach and sight of children.
- Do not store above 30°C.
- Do not take Ziagen after the expiry date stated on the carton.
- Discard any remaining Ziagen oral solution two months after first opening.

- Disposal

Do not dispose of any unwanted medicines in your waste water or household rubbish. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

Product Description

- What it looks like

Ziagen scored tablets are yellow, biconvex, and capsule shaped. They are engraved with GX 623 on both sides.

Ziagen oral solution is a clear to slightly opalescent yellowish, aqueous solution which may turn into a brown colour over time with a fruity flavor.

- Ingredients

- Active ingredient(s)

Abacavir as abacavir sulfate

- Inactive ingredient(s)

Tablet Core

Microcrystalline cellulose
Sodium starch glycollate (Type A)
Magnesium stearate
Colloidal anhydrous silica

Tablet Coating

Opadry yellow YS-1-12789-A
Purified water

Oral Solution

Sorbitol
Saccharin sodium
Sodium citrate
Citric acid anhydrous
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Polyethylene glycol

Artificial strawberry and banana flavor
Hydrochloric acid, dilute and/or
solution of sodium hydroxide
Purified water

- *MAL number*

Ziagen Tablet

- MAL20001015ACRZ

Ziagen Oral Solution

- MAL20001014ACRZ

Manufacturer

Ziagen Tablet

Delpharm Poznań Spółka Akcyjna
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Poland

Ziagen Oral Solution

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