

## Package leaflet: Information for the user

### Ziagen 20 mg/ml oral solution abacavir

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **IMPORTANT - Hypersensitivity reactions**

**Ziagen contains abacavir** (which is also an active substance in medicines such as **Kivexa**, **Triumeq** and **Trizivir**). Some people who take abacavir may develop a **hypersensitivity reaction** (a serious allergic reaction), which can be life-threatening if they continue to take abacavir containing products.

**You must carefully read all the information under ‘Hypersensitivity reactions’ in the panel in Section 4.**

The Ziagen pack includes an **Alert Card**, to remind you and medical staff about abacavir hypersensitivity. **Detach this card and keep it with you at all times.**

#### **What is in this leaflet**

1. What Ziagen is and what it is used for
2. What you need to know before you take Ziagen
3. How to take Ziagen
4. Possible side effects
5. How to store Ziagen
6. Contents of the pack and other information

#### **1. What Ziagen is and what it is used for**

**Ziagen is used to treat HIV (human immunodeficiency virus) infection.**

Ziagen contains the active ingredient abacavir. Abacavir belongs to a group of anti-retroviral medicines called *nucleoside analogue reverse transcriptase inhibitors (NRTIs)*.

Ziagen does not completely 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 cell 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.

#### **2. What you need to know before you take Ziagen**

### **Do not take Ziagen:**

- if you are **allergic** (*hypersensitive*) to abacavir (or any other medicine containing abacavir - such as **Triumeq, Trizivir** or **Kivexa**) or any of the other ingredients of this medicine (listed in Section 6)

**Carefully read all the information about hypersensitivity reactions in Section 4.**

**Check with your doctor** if you think this applies to you.

### **Take special care with Ziagen**

Some people taking Ziagen for HIV are more at risk of serious side effects. You need to be aware of the extra risks:

- if you have moderate or **severe liver disease**
- if you have ever had **liver disease**, including hepatitis B or C
- if you are seriously **overweight** (especially if you are a woman)
- if you have **severe kidney disease**

**Talk to your doctor if any of these apply to you.** You may need extra check-ups, including blood tests, while you are taking your medicine. **See Section 4 for more information.**

#### Abacavir hypersensitivity reactions

Even patients who don't have the HLA-B\*5701 gene may still develop a **hypersensitivity reaction** (a serious allergic reaction).

**Carefully read all the information about hypersensitivity reactions in Section 4 of this leaflet.**

### **Risk of cardiovascular events**

It cannot be excluded that abacavir may increase the risk of having cardiovascular events.

**Tell your doctor** if you have cardiovascular problems, if you smoke, or have other illnesses that may increase your risk of cardiovascular diseases such as high blood pressure, or diabetes. Do not stop taking Ziagen unless your doctor advises you to do so.

### **Look out for important symptoms**

Some people taking medicines for HIV infection develop other conditions, which can be serious. You need to know about important signs and symptoms to look out for while you are taking Ziagen.

**Read the information 'Other possible side effects of combination therapy for HIV' in Section 4 of this leaflet.**

### **Other medicines and Ziagen**

**Tell your doctor or pharmacist if you are taking any other medicines**, or if you have taken any recently, including herbal medicines or other medicines you bought without a prescription. Remember to tell your doctor or pharmacist if you begin taking a new medicine while you are taking Ziagen.

### **Some medicines interact with Ziagen**

These include:

- **phenytoin**, for treating **epilepsy**.  
**Tell your doctor** if you are taking phenytoin. Your doctor may need to monitor you while you are taking Ziagen.
- **methadone** used as a **heroin substitute**. Abacavir increases the rate at which methadone is removed from the body. If you are taking methadone, you will be checked for any withdrawal symptoms. Your methadone dose may need to be changed.  
**Tell your doctor** if you are taking methadone.
- **Riociguat**, for treating **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 may increase riociguat blood levels.

### **Pregnancy**

**Ziagen is not recommended for use during pregnancy.** Ziagen and similar medicines may cause side effects in unborn babies. If you have taken Ziagen during your pregnancy, your doctor may request regular blood tests and other diagnostic tests to monitor the development of your child. In children whose mothers took NRTIs during pregnancy, the benefit from the protection against HIV outweighed the risk of side effects.

### **Breast-feeding**

Breast-feeding **is not recommended** in women living with HIV because HIV infection can be passed on to the baby in breast milk. A small amount of the ingredients in Ziagen can also pass into your breast milk.

If you are breast-feeding, or thinking about breast-feeding, **you should discuss it with your doctor as soon as possible.**

### **Driving and using machines**

**Do not drive or operate machines** unless you are feeling well.

### **Important information about some of the other ingredients of Ziagen oral solution**

This medicine contains the sweetener sorbitol (approximately 5g in each 15 ml dose), which may have a mild laxative effect. Do not take medicines containing sorbitol if you have hereditary fructose intolerance. The calorific value of sorbitol is 2.6 kcal/g.

Ziagen also contains preservatives (*parahydroxybenzoates*) which may cause allergic reactions (possibly delayed).

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

Ziagen oral solution contains 50 mg/ml of propylene glycol. When taken according to the dosage recommendations each 15 ml dose contains approximately 750 mg of propylene glycol.

If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.

If you are pregnant or breast-feeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

## **3. How to take Ziagen**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Ziagen can be taken with or without food.

### **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 do not stop taking Ziagen** without your doctor's advice.

## How much to take

### Adults, adolescents and children weighing at least 25 kg

The usual dose of Ziagen is 600 mg (30 ml) a day. This can be taken either as 300 mg (15 ml) twice a day or 600 mg (30 ml) once a day.

### Children from 3 months of age weighing less than 25 kg

The dose depends on the child's body weight. The recommended dose is 8 mg/kg twice a day or 16 mg/kg once a day, up to a maximum total daily dose of 600 mg daily.

## How to measure the dose and take the medicine

Use the oral dosing syringe supplied with the pack to measure your dose accurately. When full, the syringe contains 10 ml of solution.

1. Remove the plastic wrap from the syringe/adaptor
2. **Remove the bottle cap.** Keep it safely.
3. Remove the adaptor from the syringe.
4. Hold the bottle firmly. **Push the plastic adaptor into the neck of the bottle**
5. **Insert the syringe** firmly into the adaptor
6. Turn bottle upside down
7. **Pull out the syringe plunger** until the syringe contains the first part of your full dose
8. Turn the bottle the right way up. **Remove the syringe** from the adaptor
9. **Put the syringe into your mouth**, placing the tip of the syringe against the inside of your cheek. **Slowly push the plunger in**, allowing time to swallow. **Don't** push too hard and squirt the liquid into the back of your throat, or you may choke
10. **Thoroughly clean the syringe each time it has been emptied**
11. **Repeat steps 5 to 10** in the same way until you have taken your whole dose. *For example, if your dose is 30 ml, you need to take 3 syringe-fulls of medicine*
12. After you have taken your complete dose, wash the syringe thoroughly in clean water. Let it dry completely before you use it again
13. **Close the bottle** tightly with the cap, leaving the adaptor in place

## If you take more Ziagen than you should

If you accidentally take too much Ziagen, tell your doctor or your pharmacist, or contact your nearest hospital emergency department for further advice.

## If you forget to take Ziagen

If you forget to take a dose, take it as soon as you remember. Then continue your treatment as before. Do not take a double dose to make up for a forgotten dose.

It is important to take Ziagen regularly, because if you take it at irregular intervals, you may be more likely to have a hypersensitivity reaction.

## If you have stopped taking Ziagen

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 taking it again.** Your doctor will check whether your symptoms were related to a hypersensitivity reaction. If the doctor thinks they may have been related, **you will be told never again to take Ziagen, or any other medicine containing abacavir (e.g. Triumeq, Trizivir or Kivexa).** It is important that you follow this advice.

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.

#### 4. Possible side effects

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

Like all medicines, this medicine can cause side effects, although not everyone gets them.

When you are 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.**

Even patients who don't have the HLA-B\*5701 gene may still develop **a hypersensitivity reaction** (a serious allergic reaction), described in this leaflet in the panel headed 'Hypersensitivity reactions'.

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

**As well as the side effects listed below for Ziagen**, other conditions can develop during combination therapy for HIV.

It is important to read the information later in this section under 'Other possible side effects of combination therapy for HIV'.

#### **Hypersensitivity reactions**

**Ziagen** contains **abacavir** (which is also an active substance in **Kivexa**, **Triumeq** and **Trizivir**). Abacavir can cause a serious allergic reaction known as a hypersensitivity reaction. These hypersensitivity reactions have been seen more frequently in people taking medicines that contain abacavir.

#### **Who gets these reactions?**

Anyone taking Ziagen could develop a hypersensitivity reaction to abacavir, which could be life threatening if they continue to take Ziagen.

You are more likely to develop such a reaction if you have the **HLA-B\*5701** gene (but you can get a reaction even if you do not have this gene). You should have been tested for this gene before Ziagen was prescribed for you. **If you know you have this gene, tell your doctor before you take Ziagen.**

About 3 to 4 in every 100 patients treated with abacavir in a clinical trial who did not have the HLA-B\*5701 gene developed a hypersensitivity reaction.

#### **What are the symptoms?**

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

Other symptoms include:

Pains in the joints or muscles, swelling of the neck, shortness of breath, sore throat, cough, occasional headaches, inflammation of the eye (conjunctivitis), mouth ulcers, low blood pressure, tingling or numbness of the hands or feet.

#### **When do these reactions happen?**

Hypersensitivity reactions can start at any time during treatment with Ziagen, but are more likely during the first 6 weeks of treatment.

**If you are caring for a child who is being treated with Ziagen, it is important that you understand the information about this hypersensitivity reaction. If your child gets the symptoms described below it is essential that you follow the instructions given.**

**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 abdominal pain
  - severe tiredness or achiness, or generally feeling ill

**Your doctor may advise you to stop taking Ziagen.**

**If you have stopped taking Ziagen**

If you have stopped taking Ziagen because of a hypersensitivity reaction, **you must NEVER AGAIN take Ziagen, or any other medicine containing abacavir (e.g. Trizivir, Triumeq or Kivexa).** If you do, within hours, your blood pressure could fall dangerously low, which could result in death.

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 (e.g. Trizivir, Triumeq or Kivexa).** It is important that you follow this advice.

Occasionally, hypersensitivity reactions have developed in people who start taking abacavir containing products again, but who had only one symptom on the Alert Card before they stopped taking it.

Very rarely, patients who have taken medicines containing abacavir in the past without any symptoms of hypersensitivity have developed a hypersensitivity reaction when they start taking these medicines again.

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.

**If you are hypersensitive to Ziagen, return all your unused Ziagen oral solution for safe disposal.** Ask your doctor or pharmacist for 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.**

### **Common side effects**

These may affect **up to 1 in 10** people:

- hypersensitivity reaction
- feeling sick (*nausea*)
- headache
- being sick (*vomiting*)
- diarrhoea
- loss of appetite
- tiredness, lack of energy
- fever (high temperature)
- skin rash

### **Rare side effects**

These may affect **up to 1 in 1,000** people:

- inflammation of the pancreas (*pancreatitis*)

### **Very rare side effects**

These may affect **up to 1 in 10,000** people:

- 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*).
- lactic acidosis (excess lactic acid in the blood)

**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 gets severe or troublesome, or if you notice any side effects not listed in this leaflet.

### **Other possible side effects of combination therapy for HIV**

Combination therapy including Ziagen may cause other conditions to develop during HIV treatment.

### **Symptoms of infection and inflammation**

#### **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. Symptoms usually include **fever**, plus some of the following:

- headache
- stomach ache
- difficulty breathing

In rare cases, as the immune system becomes stronger, it can also attack healthy body tissue (*autoimmune disorders*). The symptoms of autoimmune disorders may develop many months after you start taking medicine to treat your HIV infection. Symptoms may include:

- palpitations (rapid or irregular heartbeat) or tremor
- hyperactivity (excessive restlessness and movement)
- weakness beginning in the hands and feet and moving up towards the trunk of the body

If you get any symptoms of infection while you are taking Ziagen:

**Tell your doctor immediately.** Do not take other medicines for the infection without your doctor's advice.

### **You may have problems with your bones**

Some people taking combination therapy for HIV develop a condition called *osteonecrosis*. With this condition, parts of the bone tissue die because of reduced blood supply to the bone. People may be more likely to get this condition:

- if they have been taking combination therapy for a long time
- if they are also taking anti-inflammatory medicines called corticosteroids
- if they drink alcohol
- if their immune systems are very weak

- if they are overweight

**Signs of osteonecrosis include:**

- stiffness in the joints
- aches and pains (especially in the hip, knee or shoulder)
- difficulty moving

If you notice any of these symptoms:

**Tell your doctor.**

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Ziagen**

Keep this medicine out of the sight and reach of children.

Do not take this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 25°C.

Discard oral solution two months after first opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures protect the environment.

**6. Contents of the pack and other information****What Ziagen contains**

The active substance in Ziagen oral solution is 20 mg of abacavir (as sulfate) in each ml of the solution.

The other ingredients are sorbitol 70% (E420), saccharin sodium, sodium citrate, citric acid anhydrous, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), propylene glycol (E1520), maltodextrin, lactic acid, glyceryl triacetate, artificial strawberry and banana flavour, purified water, sodium hydroxide and/or hydrochloric acid for pH adjustment.

**What Ziagen looks like and contents of the pack**

Ziagen oral solution is clear to yellowish in colour which may turn into a brown colour over time with strawberry/banana flavouring. It is supplied in cartons containing a white polyethylene bottle, with a child resistant cap. The bottle contains 240 ml (20 mg abacavir/ml) of solution. A 10 ml oral dosing syringe and a plastic adapter for the bottle are included in the pack.

**Marketing Authorisation Holder:**

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**Other formats:**

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:  
0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name: Ziagen 20 mg/ml oral solution

Reference number 35728/0048

This is a service provided by the Royal National Institute of Blind People.

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