



(300mg Tablets)

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

in the section "Special Warning" under "Before you take Trizivir tablets", of this leaflet. There is also an **Alert Card** included in the Trizivir pack, to remind you and medical staff about Trizivir 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 Trizivir.**

If you have had this reaction to Trizivir, **NEVER** take Trizivir again **as WITHIN HOURS** you may experience a life-threatening lowering of your blood pressure or death.

## WHAT IS IN THIS LEAFLET?

Please read this leaflet carefully before you start taking Trizivir tablets

This leaflet answers some common questions about Trizivir tablets. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Trizivir tablets against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

## HYPERSENSITIVITY REACTION

Patients taking Trizivir may develop a hypersensitivity reaction (serious allergic reaction) which **can be life threatening** if you continue to take Trizivir. It is important you read the information on this reaction

## WHAT TRIZIVIR TABLETS ARE USED FOR

Trizivir contains abacavir, lamivudine and zidovudine which all belong to a group of medicines called antiretrovirals.

Please note that these medicines are also available separately: abacavir is Ziagen (tablets), lamivudine is 3TC™, (tablets and oral solution) and zidovudine is Retrovir™ (capsules and syrup).

Trizivir is used, alone or 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 (e.g. AIDS-related Complex or ARC).

Trizivir does not cure AIDS or HIV infection, but slows production of human immunodeficiency virus. In this way it stops ongoing damage to the body's immune system, which fights infection.

Trizivir does not reduce your risk of passing HIV infection to others. You will still be able to pass on the HIV virus by sexual activity or by passing on blood or bodily secretions which carry the HIV virus. You should continue to take all appropriate precautions.

While taking Trizivir 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 your doctor.

The long-term risks and benefits of taking Trizivir are not known. Trizivir is not addictive.

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## BEFORE YOU TAKE TRIZIVIR TABLETS

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### When you must not take them

- Do not take Trizivir tablets if you have ever had an allergic reaction to abacavir (trade name Ziagen), lamivudine (trade name 3TC) or zidovudine (trade name Retrovir), or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following: wheezing, swelling of the lips/mouth, difficulty in breathing, hay fever, lumpy rash ("hives") or fainting.

## SPECIAL WARNING

### Hypersensitivity reaction (serious allergic reaction):

About 4 in every 100 patients, who are treated with abacavir (Ziagen), develop a hypersensitivity reaction. 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 TRIZIVIR.** 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 abacavir, and get worse with continued treatment.

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

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

- Do not take Trizivir tablets if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.

Your doctor should discuss with you the risks and benefits of using Trizivir tablets if you are pregnant or breastfeeding.

### **Do not take Trizivir if you have:**

- kidney disease
- liver disease or reduced liver function
- reduced red blood cell count (anaemia),
- reduced white blood cell count (neutropenia).

If you have certain health conditions, your doctor may advise that you take a lower dose of lamivudine and/or zidovudine, the active ingredients in Trizivir tablets. The separate products should be used in these cases. Ask your doctor if you are not sure whether you should take Trizivir.

- Do not take Trizivir tablets after the expiry date (EXP) printed on the pack.

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

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

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

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## **BEFORE YOU START TO TAKE TRIZIVIR**

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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.
- you are taking or have taken any other medicines.

### **When you stop taking Trizivir Tablets**

If you have a long-standing viral infection of your liver (hepatitis B) it may flare up. This can cause serious illness particularly if your liver is already not working very well. If you have both HIV and hepatitis B, when you stop taking your Trizivir tablets, your doctor is likely to arrange tests from time to time to check how well your liver is working and to measure virus levels.

### **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.

There is little information about the way other medicines might affect the way that Trizivir works, or how Trizivir affects other medicines. Particular care is needed when taking the painkiller, paracetamol. Your doctor or pharmacist will be able to tell you what to do when taking Trizivir with other medicines.

### **Use in children**

Trizivir is not recommended for use in children under 12 years of age. Because it is a fixed dose combination tablet it cannot be adjusted according to the size and weight of the patient.

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## **HOW TO TAKE TRIZIVIR TABLETS**

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

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

### **How much to take**

The usual dosage of Trizivir tablets is one tablet, twice a day.

### **How to take them**

Your Trizivir tablets should be swallowed with a drink of water.

### **When to take them**

Your doctor or pharmacist will be able to tell you when you should take your Trizivir tablets.

### **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.

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## **IF YOU TAKE TOO MUCH (OVERDOSE)**

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**Immediately telephone your doctor or Poisons Information Centre (0800 764 766) or go to accident and emergency at your nearest hospital, if you think you or anyone else may have taken too many Trizivir tablets. Do this even if there are no signs of discomfort or poisoning. You 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.

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## **WHILE YOU ARE TAKING TRIZIVIR TABLETS**

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### **Things you must do**

Tell your doctor or pharmacist that you are taking Trizivir tablets if you are about to be started on any new medicines.

There is little information about the way other medicines might affect the way that Trizivir works. You must tell your doctor or pharmacist that you are taking Trizivir before you start taking medicines you buy from a pharmacy, health food shop or supermarket. This is especially important regarding medicines which might have an effect on the kidneys, liver, red or white blood cells or other body cells.

Tell your doctor if you become pregnant or are trying to become 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 Trizivir 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 Trizivir tablets to treat any other complaints unless your doctor says to.

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

Do not give this medicine to children under 12 years of age. Because it is a fixed dose combination tablet it cannot be adjusted according to the size and weight of the patient.

### Things to be careful of

Be careful driving or operating machinery until you know how Trizivir tablets affect you.

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## POSSIBLE SIDE EFFECTS

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Check with your doctor as soon as possible if you have any problems while taking Trizivir tablets, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Trizivir tablets can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and 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 abacavir (Ziagen) a component of Trizivir. This is described in the section "Special Warnings" under "Before you take your Trizivir tablets", of this leaflet.** It is important that you read and understand the information about this serious reaction.

### Other side-effects associated with Trizivir 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 TRIZIVIR 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.

### Other serious side-effects include:

- reduced red blood cell count (anaemia).
- reduced white blood cell count (neutropenia).

The frequency and severity of anaemia and neutropenia are greater in patients with advanced HIV disease, or in patients who start taking Trizivir in later stages of HIV disease.

While you are taking Trizivir, it is very important that your doctor keeps a close check on your health and takes blood samples to monitor levels of red and white blood cells. If you develop anaemia or neutropenia, your doctor may reduce or stop the dose of Trizivir, or recommend standard treatment for these conditions. Ask your doctor any questions you may have.

It is not known whether many of these side effects are due to taking Trizivir or taking Trizivir while taking other medicines. Some of these symptoms may occur as part of HIV infection, AIDS or AIDS-related Complex.

The side effects listed below have been reported:

- sweating, chills, swelling of lips and/or tongue, flu-like symptoms, fever, increased sensitivity to pain, back pain, enlarged glands, chest pain, weakness, weight loss, generally feeling unwell.
- constipation, difficulty in swallowing, gas from stomach or bowel, mouth ulcers,



heartburn, vomiting, loss or reduction in appetite, nausea.

- abdominal discomfort and pain.
- muscle aches or pains, muscle shaking or spasm or twitching, muscle disease, joint pain
- enlarged fatty liver, abnormal results of blood tests of liver function, inflammation of the pancreas.
- confusion, depression, nervousness, fainting, loss of mental clarity, dizziness, seizures, severe headache, sleeplessness, fatigue/tiredness.
- cough, sore throat, hay fever, sinus problems, hoarseness.
- itchiness, skin rash conjunctivitis.
- changes in nail, skin or mouth colour.
- passing too much urine, pain, difficulty or increased frequency of passing urine.
- reduction in all blood cells.
- increased bruising or bleeding.
- blood chemistry changes, with excess acidity of the blood.
- unusual feelings in any part of the body, such as numbness, burning, tingling or pins and needles.
- Convulsions

Ask your doctor or pharmacist any questions you may have. If you experience any of these side-effects, and they concern you, see your doctor or pharmacist.

If you have any of the following symptoms soon after starting to take your medicine, do not take any more Trizivir tablets and tell your doctor immediately or go to the accident and emergency department at your nearest hospital.

- Severe stomach pain or cramps.
- Nausea.
- Vomiting.

These side effects may be due to a condition called pancreatitis.

If you are on medication for HIV and become very sick, with fast breathing, stop taking Trizivir tablets and consult your doctor immediately. You may have a condition known as "lactic acidosis". 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.

See your doctor if you feel generally unwell with loss of appetite, nausea, vomiting, itching, yellowness of the skin or eyes or dark coloured urine, or if the blood tests of your liver function are abnormal. It is likely you will have to stop taking Trizivir tablets.

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.

Side-effects may depend on whether you take Trizivir alone, or also have taken other antiretroviral medication(s). Less is known about possible side-effects of taking Trizivir with other antiretrovirals.

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

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.

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## AFTER TAKING TRIZIVIR TABLETS

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### Storage

Keep this medicine where young children cannot reach them.

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

Keep Trizivir 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 Trizivir tablets in their pack until it is time to take them.

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

## Disposal

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

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## PRODUCT DESCRIPTION

### What Trizivir tablets looks like

Trizivir tablets are blue/green capsule shaped film coated tablets with "GXLL1" engraved on one side

### Ingredients

Trizivir contains the active ingredients:

- abacavir 300mg as abacavir sulphate
- lamivudine (150 mg)
- zidovudine (300 mg)

Trizivir tablets also contain the following inactive ingredients:

- microcrystalline cellulose,
- sodium starch glycollate,
- magnesium stearate,
- Opadry green 03B11434,
- hypromellose,
- titanium dioxide,
- polyethylene glycol,
- indigo carmine aluminium lake,
- iron oxide yellow.

## Manufacturer

Your Trizivir tablets are distributed by:

Glaxo Wellcome New Zealand Ltd  
Quay Tower  
Cnr Albert and Customs St  
Private Bag 106600  
Downtown Auckland  
New Zealand

Ph (09) 367-2900

Fax (09) 367-2910

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## FURTHER INFORMATION

This is not all the information that is available on Trizivir 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 advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

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

This leaflet was prepared on March 6<sup>th</sup> 2002 (Issue 1).

The information provided applies only to: Trizivir tablets™

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