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Package leaflet: Information for the user
Abacavir 300 mg Film-Coated Tablets

Abacavir

Read all of this leaflet carefully before you start using 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

Abacavir tablets contain 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 Abacavir pack includes an **Alert Card**, to remind you and medical staff about abacavir hypersensitivity. **Keep this card with you at all times**.

What is in this leaflet:

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

1. What Abacavir is and what it is used for

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

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

Abacavir 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 Abacavir in the same way. Your doctor will monitor the effectiveness of your treatment.

2. What you need to know before you use Abacavir

Do not take Abacavir:
- if you are allergic *(hypersensitive)* to abacavir (or any other medicine containing abacavir –such as **Trizivir, Triumeq** 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 Abacavir
Some people taking Abacavir 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 heart attack
It cannot be excluded that abacavir may increase the risk of having a heart attack.
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. Do not stop taking Abacavir 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 Abacavir.
Read the information 'Other possible side effects of combination therapy for HIV' in Section 4 of this leaflet.

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.

Other medicines and Abacavir
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 Abacavir.

Some medicines interact with Abacavir
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 Abacavir.
- **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.

Pregnancy
Abacavir is not recommended for use during pregnancy. Abacavir and similar medicines may cause side effects in unborn babies. If you have taken Abacavir 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
Women who are HIV-positive must not breast-feed, because HIV infection can be passed on to the baby in breast milk. A small amount of the ingredients in Abacavir can also pass into your breast milk.
If you are breast-feeding, or thinking about breast-feeding:
Talk to your doctor immediately.

Driving and using machines
Do not drive or operate machines unless you are feeling well.

3. How to use Abacavir

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the tablets with some water. Abacavir can be taken with or without food.

If you cannot swallow the tablets, you may crush and combine them with a small amount of food or drink, and take all the dose immediately.

Stay in regular contact with your doctor
Abacavir 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 Abacavir without your doctor's advice.

How much to take
Adults, adolescents and children weighing at least 25 kg
The usual dose of Abacavir is 600 mg a day. This can be taken either as one 300 mg tablet twice a day or two 300 mg tablets once a day.

Children from one year of age weighing less than 25 kg
The dose given depends on the body weight of your child. The recommended dose is:
- **Children weighing at least 20 kg and less than 25 kg:** The usual dose of Abacavir is 450 mg a day. This can be given as 150 mg (half of a tablet) taken in the morning and 300 mg (one whole tablet) taken in the evening, or 450 mg (one and a half tablets) once a day as advised by your doctor.
- **Children weighing at least 14 kg and less than 20 kg:** The usual dose of Abacavir is 300 mg a day. This can be given as 150 mg (half of a tablet) twice daily, or 30 mg (one whole tablet) once a day as advised by your doctor.

The tablet can be divided into equal doses.

An oral solution (20 mg abacavir/ml) is also available for the treatment of children over three months of age and weighing less than 14 kg, or for people who need a lower than usual dose, or who cannot take tablets.

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

If you forget to take Abacavir
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 Abacavir regularly, because if you take it at irregular intervals, you may be more likely to have a hypersensitivity reaction.

If you have stopped taking Abacavir
If you have stopped taking Abacavir 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 Abacavir, 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 Abacavir 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 Abacavir 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 Abacavir, 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
Abacavir tablets contain **abacavir** (which is also an active substance in **Trizivir, Triumeq** and **Kivexa**).

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

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 Abacavir was prescribed for you. **If you know you have this gene, tell your doctor before you take Abacavir.**
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 Abacavir, but are more likely during the first 6 weeks of treatment.

If you are caring for a child who is being treated with Abacavir, 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 Abacavir.

If you have stopped taking Abacavir
If you have stopped taking Abacavir because of a hypersensitivity reaction, **you must NEVER AGAIN take Abacavir, 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 Abacavir 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 Abacavir, 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 Abacavir 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 Abacavir, return all your unused Abacavir tablets for safe disposal. Ask your doctor or pharmacist for advice.

The Abacavir pack includes an **Alert Card**, to remind you and medical staff about hypersensitivity reactions. **Keep this card with you at all times.**

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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 Abacavir 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 Abacavir:
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 at 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 Abacavir

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

Do not use this medicine after the expiry date which is stated on the carton and the blister or bottle label after EXP. The expiry date refers to the last day of that month.

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 will help protect the environment.

6. Contents of the pack and other information

What Abacavir contains
The active substance in each Abacavir film-coated, scored tablet is 300 mg of abacavir.
The other ingredients are:
Tablet core: cellulose, microcrystalline PH102, sodium starch glycolate (type A), silica, colloidal anhydrous, magnesium stearate
Tablet coating: hypromellose 2910 (E464), titanium dioxide (E171), Triacetin, Iron oxide yellow (E172) and polysorbate 80 (E433).

What Abacavir looks like and contents of the pack
Abacavir film-coated tablets are debossed with "H" on one side and with 'A' and '26' on the other side separated by the score line. The tablets are yellow and capsule-shaped and are provided in blister packs or bottles containing 60 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Dr. Reddy's Laboratories (UK) Ltd., 6 Riverview Road, Beverley, East Yorkshire, HU17 0LD, United Kingdom

Manufacturer
Pharmadox Healthcare Limited, KW20A Kordin Industrial Park, Paola, PLA 3000, Malta

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