Package leaflet: Information for the user

Abacavir/Lamivudine 600 mg/300 mg film-coated tablets

abacavir/lamivudine

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
Abacavir/Lamivudine contains abacavir. 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/Lamivudine 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 Abacavir/Lamivudine is and what it is used for

Abacavir/Lamivudine is used to treat HIV (human immunodeficiency virus) infection in adults, adolescents and in children weighing at least 25 kg.

Abacavir/Lamivudine contains two active ingredients that are used to treat HIV infection: abacavir and lamivudine. These belong to a group of anti-retroviral medicines called *nucleoside analogue reverse transcriptase inhibitors (NRTIs)*.

Abacavir/Lamivudine 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 cells that are important in helping your body to fight infection.

Not everyone responds to treatment with Abacavir/Lamivudine in the same way. Your doctor will monitor the effectiveness of your treatment.

2. What you need to know before you take Abacavir/Lamivudine

Do not take Abacavir/Lamivudine
- if you are **allergic** (hypersensitive) to abacavir (or any other medicine containing abacavir, lamivudine 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. **Do not take Abacavir/Lamivudine**.

Warnings and precautions
Some people taking Abacavir/Lamivudine or other combination treatments 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 have hepatitis B infection, do not stop Abacavir/Lamivudine without your doctor's advice, as your hepatitis may come back)
- if you are seriously **overweight** (especially if you are a woman)
- if you have **a kidney problem**

Talk to your doctor if any of these apply to you before using Abacavir/Lamivudine. 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/Lamivudine 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/Lamivudine.
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/Lamivudine
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, 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/Lamivudine.

These medicines should NOT be used with Abacavir/Lamivudine:

- Emtricitabine, to treat **HIV infection**
- other medicinal products containing lamivudine, used to treat **HIV infection** or **hepatitis B infection**
- high doses of **trimethoprim/sulfamethoxazole**, an antibiotic
- cladribine, used to treat **hairy cell leukaemia.**

Tell your doctor if you are being treated with any of these.

Some medicines interact with Abacavir/Lamivudine
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/Lamivudine.

- **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.

- medicines (usually liquids) containing **sorbitol and other sugar alcohols** (such as xylitol, mannitol, lactitol or maltitol), if taken regularly.
  Tell your doctor or pharmacist if you are taking any of these.

Pregnancy
Abacavir/Lamivudine is NOT recommended for use during pregnancy. Abacavir/Lamivudine and similar medicines may cause side effects in unborn babies. If you have taken Abacavir/Lamivudine 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/Lamivudine 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
Abacavir/Lamivudine may cause side effects which could affect your ability to drive or use machines. **Talk to your doctor** about your ability to drive or operate machines while taking Abacavir/Lamivudine.

3. How to take Abacavir/Lamivudine

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

The recommended dose of Abacavir/Lamivudine for adults, adolescents and children weighing 25 kg or more is one tablet once a day.

Swallow the tablets whole, with some water. Abacavir/Lamivudine can be taken with or without food.

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

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

If you forget to take Abacavir/Lamivudine
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/Lamivudine 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/Lamivudine
If you have stopped taking Abacavir/Lamivudine 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/Lamivudine, or any other medicine containing abacavir**. It is important that you follow this advice.

If your doctor advises that you can start taking Abacavir/Lamivudine 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 everybody gets them.

When you are being treated for HIV, it can be hard to tell whether a symptom is a side effect of Abacavir/Lamivudine 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/Lamivudine, 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/Lamivudine contains **abacavir**. 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/Lamivudine could develop a hypersensitivity reaction to abacavir, which could be life threatening if they continue to take Abacavir/Lamivudine.

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

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/Lamivudine, but are more likely during the first 6 weeks of treatment.

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/Lamivudine.

If you have stopped taking Abacavir/Lamivudine
If you have stopped taking Abacavir/Lamivudine because of a hypersensitivity reaction, **you must NEVER AGAIN take Abacavir/Lamivudine, or any other medicine containing abacavir**. If you do, within hours, your blood pressure could fall dangerously low, which could result in death.

If you have stopped taking Abacavir/Lamivudine 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/Lamivudine, or any other medicine containing abacavir**. 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/Lamivudine 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/Lamivudine, return all your unused Abacavir/Lamivudine tablets for safe disposal. Ask your doctor or pharmacist for advice.

The Abacavir/Lamivudine 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
- headache
- being sick (*vomiting*)
- feeling sick (*nausea*)
- diarrhoea
- stomach pains
- loss of appetite
- tiredness, lack of energy
- fever (high temperature)
- general feeling of being unwell
- difficulty in sleeping (*insomnia*)
- muscle pain and discomfort
- joint pain
- cough
- irritated or runny nose
- skin rash
- hair loss.

Uncommon side effects
These may affect **up to 1 in 100** people and may show up in blood tests:
- a low red blood cell count (*anaemia*) or low white blood cell count (*neutropenia*)
- an increase in the level of liver enzymes
- a decrease in the number of cells involved in blood clotting (*thrombocytopenia*).

Rare side effects
These may affect **up to 1 in 1000** people:
- liver disorders, such as jaundice, enlarged liver or fatty liver, inflammation (*hepatitis*)
- inflammation of the pancreas (*pancreatitis*)
- breakdown of muscle tissue.

Rare side effects that may show up in blood tests are:
- increase in an enzyme called *amylase*.

Very rare side effects
These may affect **up to 1 in 10,000** people:
- numbness, tingly feelings in the skin (pins and needles)
- sensation of weakness in the limbs
- 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.

Very rare side effects that may show up in blood tests are:
- a failure of the bone marrow to produce new red blood cells (*pure red cell aplasia*).

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 such as Abacavir/Lamivudine 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*). Such infections may have been "silent" and not detected by the weak immune system before treatment was started. After starting treatment, the immune system becomes stronger, and may attack the infections, which can cause symptoms of infection or inflammation. 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 and inflammation or if you notice any of the symptoms above:
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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6767836; Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Abacavir/Lamivudine

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 blister 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/Lamivudine contains

- The active substances are abacavir and lamivudine.
  Each film-coated tablet contains 600 mg of abacavir and 300 mg of lamivudine.
- The other ingredients are:
  - Tablet core: microcrystalline cellulose, hydroxypropyl cellulose, sodium starch glycolate (type A) and magnesium stearate.
  - Film-coat: hypromellose, macrogol 4000, titanium dioxide (E171), polysorbate 80, iron oxide yellow (E172) and iron oxide red (E172).

What Abacavir/Lamivudine looks like and contents of the pack

Abacavir/Lamivudine film-coated tablets are orange, oblong, and biconvex with debossing 600 on one side and 300 on the other side with dimension of ~ 20.5 mm x 9 mm.

Abacavir/Lamivudine is available in pack sizes of 10, 30 and 90 film-coated tablets in blisters or 10x1, 30x1 and 90x1 film-coated tablets in perforated unit-dose blisters.

Not all pack sizes may be marketed.

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