Package leaflet: Information for the user

Abacavir/Lamivudine Mylan 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 Mylan contains abacavir (which is also an active substance in medicines such as **Trizivir, Triumeq** and **Ziagen**). 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 Mylan 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/Lamivudine Mylan is and what it is used for

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

Abacavir/Lamivudine Mylan 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 Mylan 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 Mylan

Do not take Abacavir/Lamivudine Mylan:

- if you are **allergic** *(hypersensitive)* to abacavir (or any other medicine containing abacavir - (e.g. **Trizivir, Triumeq** or **Ziagen**), 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.
- if you have **severe liver disease**

Check with your doctor if you think any of these apply to you. **Do not take Abacavir/Lamivudine Mylan.**

Take special care with Abacavir/Lamivudine Mylan
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 ever had **liver disease**, including hepatitis B or C (if you have hepatitis B infection, do not stop Abacavir/Lamivudine Mylan without your doctor's advice, as your hepatitis may come back)
- if you are seriously **overweight** (especially if you are a woman)
- if you are **diabetic** and using insulin
- if you have a **kidney problem**

Talk to your doctor if any of these apply to you before using Abacavir/Lamivudine Mylan. 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 do not 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 Mylan 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 Mylan.
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 Mylan
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/Lamivudine Mylan.

These medicines should not be used with Abacavir/Lamivudine Mylan:

- 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 Mylan
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 Mylan.

- **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.

- **ribavirin,** for treating **hepatitis C.** Abacavir may make the combination of ribavirin and pegylated interferon less effective at reducing levels of hepatitis C virus in the body.
  Tell your doctor if you are taking ribavirin.

Pregnancy
Abacavir/Lamivudine Mylan 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.

If you are pregnant, if you become pregnant, or if you are planning to become pregnant:
Talk to your doctor immediately about the risks and benefits of taking Abacavir/Lamivudine Mylan, or other medicines for treating HIV infection, during your pregnancy.

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 Mylan 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 Mylan 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 Mylan.

Important information about some of the other ingredients of Abacavir/Lamivudine Mylan
Abacavir/Lamivudine Mylan contains a colouring called sunset yellow (E110), this may cause allergic reactions in some people.

3. How to take Abacavir/Lamivudine Mylan

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 Mylan 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 Mylan can be taken with or without food.

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

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

If you forget to take Abacavir/Lamivudine Mylan
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 Mylan 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 Mylan
If you have stopped taking Abacavir/Lamivudine Mylan 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 Mylan, or any other medicine containing abacavir (e.g. Trizivir or Ziagen)**. It is important that you follow this advice.

If your doctor advises that you can start taking Abacavir/Lamivudine Mylan 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

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/Lamivudine Mylan 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 do not 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 Mylan, 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 Mylan contains **abacavir** (which is also an active substance in medicines such as **Trizivir, Triumeq** and **Ziagen**). 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 Mylan could develop a hypersensitivity reaction to abacavir, which could be life threatening if they continue to take Abacavir/Lamivudine Mylan.

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 Mylan was prescribed for you. **If you know you have this gene, tell your doctor before you take Abacavir/Lamivudine Mylan.**

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.

If you continue to take Abacavir/Lamivudine Mylan, the symptoms will get worse, and may be life-threatening.

When do these reactions happen?

Hypersensitivity reactions can start at any time during treatment with Abacavir/Lamivudine Mylan, 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 Mylan.

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

If you have stopped taking Abacavir/Lamivudine Mylan 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 Mylan, or any other medicine containing abacavir (e.g. Trizivir, Triumeq or Ziagen)**. 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 Mylan 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 Mylan tablets for safe disposal. Ask your doctor or pharmacist for advice.

The Abacavir/Lamivudine Mylan pack includes an **Alert Card**, to remind you and medical staff about hypersensitivity reactions. **This card contains important safety information, 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*)
- lactic acidosis (*see the next section, 'Other possible side effects of combination therapy for HIV'*)
- 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)*.

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.

Your body shape may change

People taking combination therapy for HIV may find that their body shape changes, because of changes in fat distribution:
- Fat may be lost from the legs, arms or face.
- Extra fat may build up around the tummy (abdomen), or on the breasts or internal organs.
- Fatty lumps (sometimes called buffalo hump) may appear on the back of the neck.

It is not yet known what causes these changes, or whether they have any long-term effects on your health. If you notice changes in your body shape:
Tell your doctor.

Lactic acidosis is a rare but serious side effect

Some people taking abacavir/lamivudine, 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, or in obese (very overweight) people, especially women.

Signs of lactic acidosis include:
- feeling sick (*nausea*), being sick (*vomiting*)
- stomach pain
- generally feeling unwell
- loss of appetite, weight loss
- deep, rapid, difficult breathing
- numbness or weakness in the limbs

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.

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.

Other effects may show up in blood tests

Combination therapy for HIV can also cause:
- increased levels of lactic acid in the blood, which on rare occasions can lead to lactic acidosis
- increased levels of sugar and fats (*triglycerides* and *cholesterol*) in the blood
- resistance to insulin (so if you are diabetic, you may have to change your insulin dose to control your blood sugar).

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 6762517.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 Mylan

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 after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

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 Mylan contains
The active substances in each Abacavir/Lamivudine Mylan film-coated tablet are abacavir hydrochloride equivalent to 600 mg abacavir and 300 mg of lamivudine.

The other ingredients are microcrystalline cellulose, crospovidone (Type A), povidone (K-30), iron oxide yellow (E172) and magnesium stearate in the core of the tablet. The tablet coating contains hypromellose HPMC 2910 -3mPas, hypromellose HPMC 2910 -6mPas, titanium dioxide (E171), macrogol 400, polysorbate 80 and sunset yellow aluminium lake (E110).

What Abacavir/Lamivudine Mylan looks like and contents of the pack
Abacavir/Lamivudine Mylan are orange coloured, capsule shaped, biconvex, 20.6 mm x 9.1 film-coated tablets, engraved with “300” on one side and “600” on other side.

Abacavir/Lamivudine Mylan are supplied in blister packs containing 30, 60 or 90 film-coated tablets, perforated unit dose blister packs containing 30 x 1 film-coated tablets or multi blister packs containing 60 or 90 film-coated tablets.
30 film-coated tablets in bottles containing an activated carbon sachet or an activated carbon sachet and oxygen absorber to control the moisture in the bottle.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Manufacturer

Hormosan Pharma GmbH, Wilhelmshöher Str. 106, D-60389, Frankfurt/Main, Germany.

Mylan S.A.S, 117 Allee des Parcs, 69 800 Saint Priest, France.

McDermott Laboratories Ltd. t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium	Abacavir / Lamivudine Mylan 600 mg / 300 mg filmomhulde tabletten
Denmark	Abacavir /Lamivudin Mylan
Finland	Abacavir /Lamivudin Mylan
Germany	Abacavir/Lamivudin Mylan 600 mg/300 mg Filmtabletten
Ireland	Abacavir / Lamivudine Mylan 600 mg/300 mg Film-coated Tablets
Italy	Abacavir Lamivudina Mylan
Norway	Abacavir /Lamivudin Mylan
Poland	Abacavir + Lamivudine Mylan
Portugal	Abacavir + Lamivudina Mylan
Spain	Abacavir/Lamivudina Mylan 600 mg/300 mg comprimidos recubiertos con película EFG
Sweden	Abacavir /Lamivudin Mylan
The Netherlands	Abacavir / Lamivudine Mylan 600 mg / 300 mg, filmomhulde tabletten
United Kingdom	Abacavir/Lamivudine Mylan 600 mg / 300 mg film coated tablets

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