

**Package Leaflet: Information for the patient**  
**Ablado**  
**“ABACAVIR 600 mg, DOLUTEGRAVIR 50 mg and LAMIVUDINE 300 mg TABLETS”**

**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.

**In this leaflet**

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**Abacavir, Dolutegravir Lamivudine Tablets**

Abacavir, Dolutegravir Lamivudine Tablets is a medicine that contains three active ingredients used to treat HIV infection: abacavir, lamivudine and dolutegravir. Abacavir and lamivudine belong to a group of anti-retroviral medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs), and dolutegravir belongs to a group of anti-retroviral medicines called integrase inhibitors (INIs).

The Marketing Authorisation Holder for **Abacavir, Dolutegravir Lamivudine Tablets** is:

Aurobindo Pharma Limited,  
Hyderabad, Telangana State,  
India.

**Abacavir, Dolutegravir Lamivudine Tablets are manufactured by:**

**APL Healthcare Limited,**  
Unit – IV, Plot No.16, APIIC,  
Multi Products SEZ, Menakuru Village,  
Naidupeta Mandal, Tirupati District,  
Andhra Pradesh, India.

**1. What Abacavir, Dolutegravir Lamivudine Tablets are and what it is used for**

Abacavir, Dolutegravir Lamivudine Tablets is a medicine that contains three active ingredients used to treat HIV infection: abacavir, lamivudine and dolutegravir. Abacavir and lamivudine belong to a group of anti-retroviral medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs), and dolutegravir belongs to a group of anti-retroviral medicines called integrase inhibitors (INIs).

Abacavir, Dolutegravir Lamivudine Tablets are used to treat HIV (**human immunodeficiency virus**) infection in adults and children over 12 years old who weigh at least 40 kg.

Before you are prescribed Abacavir, Dolutegravir Lamivudine Tablets your doctor will arrange a test to find out whether you carry a particular type of gene called HLA-B\*5701. Abacavir, Dolutegravir Lamivudine Tablets should not be used in patients who are known to carry the HLA-B\*5701 gene. Patients with this gene are at a high risk of developing a serious hypersensitivity (allergic) reaction if they use Abacavir, Dolutegravir Lamivudine Tablets (see ‘hypersensitivity reactions’ in section 4).

Abacavir, Dolutegravir Lamivudine Tablets does not cure HIV infection; it reduces the amount of virus in your body, and keeps it at a low level. It also increases the number of CD4 cells 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, Dolutegravir Lamivudine Tablets in the same way. Your doctor will monitor the effectiveness of your treatment.

**2. Before you take Abacavir, Dolutegravir Lamivudine Tablets**

**Do not take Abacavir, Dolutegravir Lamivudine Tablets:**

- if you are allergic (hypersensitive) to dolutegravir, abacavir (or any other medicine containing abacavir), or 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 are taking a medicine called dofetilide (to treat heart conditions).
- If you think any of these apply to you, tell your doctor.

**Warnings and Precautions**

**IMPORTANT — Hypersensitivity reactions**

Abacavir, Dolutegravir Lamivudine Tablets contains abacavir and dolutegravir. Both of these active ingredients can cause a serious allergic reaction known as a hypersensitivity reaction. You should never take abacavir or abacavir-containing products again if you have a hypersensitivity reaction: it can be life threatening.

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

The Abacavir, Dolutegravir Lamivudine Tablets pack includes an **Alert Card** to remind you and medical staff about hypersensitivity.

**Detach this card and keep it with you at all times.**

Some people taking Abacavir, Dolutegravir Lamivudine Tablets or other combination treatments for HIV are more at risk of serious side effects than others. 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, don’t stop Abacavir, Dolutegravir Lamivudine Tablets without your doctor’s advice, as your hepatitis may come back)
- if you have a kidney problem

→ **Talk to your doctor if any of these apply to you before using Abacavir, Dolutegravir Lamivudine Tablets.** You may need extra check-ups, including blood tests, while you’re 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

The possibility that abacavir increases the risk of having a heart attack cannot be excluded.

→ **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. Don’t stop taking Abacavir, Dolutegravir Lamivudine Tablets 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. These include:

- symptoms of infections and inflammation
- joint pain, stiffness and bone problems

You need to know about important signs and symptoms to look out for while you’re taking Abacavir, Dolutegravir Lamivudine Tablets.

→ **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, so it is important you take your medicine exactly as your doctor has told you. Discuss with your doctor the precautions needed to avoid infecting other people.

**Children**

This medicine is not for children under 12 years of age. The use of Abacavir, Dolutegravir Lamivudine Tablets in children under 12 years of age has not yet been studied.

**Other medicines and Abacavir, Dolutegravir Lamivudine Tablets**

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Don’t take Abacavir, Dolutegravir Lamivudine Tablets with the following medicine:

- dofetilide, used in **multiple sclerosis**

Some medicines can affect how Abacavir, Dolutegravir Lamivudine Tablets works, or make it more likely that you will have side effects. Abacavir, Dolutegravir Lamivudine Tablets can also affect how some other medicines work.

**Tell your doctor** if you are taking any of the medicines in the following list:

- metformin, to treat diabetes
- medicines called **antacids**, to treat **indigestion** and **heartburn**. **Do not take an antacid** during the 6 hours before you take Abacavir, Dolutegravir Lamivudine Tablets, or for at least 2 hours after you take it. (See also Section 3).

- supplements or multivitamins containing calcium, iron or magnesium. **If you take Abacavir, Dolutegravir Lamivudine Tablets with food**, you can take supplements or multivitamins containing calcium, iron or magnesium at the same time as Abacavir, Dolutegravir Lamivudine Tablets. **If you do not take Abacavir, Dolutegravir Lamivudine Tablets with food, do not take supplements or multivitamins containing calcium, iron or magnesium** during the 6 hours before you take, or for at least 2 hours after you take it (see also Section 3).
- emtricitabine, etravirine, efavirenz, nevirapine or tipranavir/ritonavir, to **treat HIV infection**
- medicines (usually liquids) containing sorbitol and other sugar alcohols (such as xylitol, mannitol, lactitol or maltitol), if taken regularly
- other medicines containing lamivudine, used to treat HIV infection or **hepatitis B infection**
- cladribine, used to treat **hairly cell leukaemia**
- rifampicin, to treat tuberculosis (TB) and other **bacterial infections**
- trimethoprim/sulfamethoxazole, an antibiotic to treat **bacterial infections**
- phenytoin and phenobarbital, to treat **epilepsy**
- oxcarbazepine and carbamazepine, to treat **epilepsy and bipolar disorder**
- **St. John's wort** (*Hypericum perforatum*), a herbal remedy to treat **depression**
- **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.
- Riociguat, used to treat 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.

→ **Tell your doctor or pharmacist** if you are taking any of these. Your doctor may decide to adjust your dose or that you need extra checkups.

#### **Pregnancy**

If you are pregnant, think you may be pregnant, or if you are planning to have a baby:

→ Talk to your doctor about the risks and benefits of taking.

Taking Abacavir, Dolutegravir Lamivudine Tablets at the time of becoming pregnant or during the first six weeks of pregnancy, may increase the risk of a type of birth defect, called neural tube defect, such as spina bifida (malformed spinal cord).

If you could get pregnant while receiving Abacavir, Dolutegravir Lamivudine Tablets:

→ **Talk to your doctor** and discuss whether there is a need for contraception, such as condom or pills.

Tell your doctor immediately if you become pregnant or are planning to become pregnant. Your doctor will review your treatment. Do not stop taking Abacavir, Dolutegravir Lamivudine Tablets without consulting your doctor, as this may harm you and your unborn child.

#### **Breast-feeding**

**It is recommended women who are HIV-positive do not breast-feed** because HIV infection can be passed on to the baby in breast milk.

A small amount of the ingredients in Abacavir, Dolutegravir Lamivudine Tablets 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, Dolutegravir Lamivudine Tablets can make you dizzy** and have other side effects that make you less alert.

→ **Don't drive or operate machinery** unless you are sure your alertness has not been affected.

#### **Important information about the contents of Abacavir, Dolutegravir Lamivudine Tablets.**

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

### **3. How to take Abacavir, Dolutegravir Lamivudine Tablets**

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

#### **• The usual dose is one tablet once a day**

Swallow the tablet with some liquid. Abacavir, Dolutegravir Lamivudine Tablets can be taken with or without food.

#### **Use in children and adolescents**

Children and adolescents aged between 12 and 17 years and weighing at least 40 kg can take the adult dose of one tablet once a day.

**Do not take an antacid** during the 6 hours before you take Abacavir, Dolutegravir Lamivudine Tablets, or for at least 2 hours after you take it. Other acid-lowering medicines like ranitidine and omeprazole can be taken at the same time as Abacavir, Dolutegravir Lamivudine Tablets.

→ Talk to your doctor for further advice on taking antacid medicines with Abacavir, Dolutegravir Lamivudine Tablets.

**If you take Abacavir, Dolutegravir Lamivudine Tablets with food, you can take supplements or multivitamins containing calcium, iron or magnesium** at the same time as Abacavir, Dolutegravir Lamivudine Tablets. **If you do not take Abacavir, Dolutegravir Lamivudine Tablets with food**, do not take a supplement or multivitamin containing calcium, iron or magnesium during the 6 hours before you take Abacavir, Dolutegravir Lamivudine Tablets or for at least 2 hours after you take it.

→ Talk to your doctor for further advice on taking calcium supplements, iron supplements or multivitamins with Abacavir, Dolutegravir Lamivudine Tablets.

#### **If you take more Abacavir, Dolutegravir Lamivudine Tablets than you should**

If you take too many tablets of Abacavir, Dolutegravir Lamivudine Tablets, contact your **doctor or pharmacist for advice**. If possible, show them the Abacavir, Dolutegravir Lamivudine Tablets pack.

#### **If you forget to take Abacavir, Dolutegravir Lamivudine Tablets**

If you miss a dose, take it as soon as you remember. But if your next dose is due within 4 hours, skip the dose you missed and take the next one at the usual time. Then continue your treatment as before.

→ **Don't take a double dose** to make up for a missed dose.

#### **If you have stopped taking Abacavir, Dolutegravir Lamivudine Tablets**

If you have stopped taking Abacavir, Dolutegravir Lamivudine Tablets for any reason — especially because you think you are having side effects, or because you have another 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 be related to a hypersensitivity reaction, **you will be told never again to take Abacavir, Dolutegravir Lamivudine Tablets, or any other medicine containing abacavir or dolutegravir**. It is important that you follow this advice.

If your doctor advises that you can start taking Abacavir, Dolutegravir Lamivudine Tablets 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, but not everybody gets them.

Abacavir can cause a hypersensitivity reaction (a serious allergic reaction), especially in people who carry a particular type of gene called HLA-B\*5701. Even patients who don't have the HLA-B\*5701 gene may still develop a **hypersensitivity 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, Dolutegravir Lamivudine Tablets**, other conditions can develop during combination therapy for HIV.

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

#### **Hypersensitivity Reactions**

Abacavir, Dolutegravir Lamivudine Tablets contains abacavir and dolutegravir. Both of these active ingredients 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, Dolutegravir Lamivudine Tablets could develop a hypersensitivity reaction, which could be life threatening if they continue to take Abacavir, Dolutegravir Lamivudine Tablets.

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 don't have this gene). You should have been tested for this gene before Abacavir, Dolutegravir Lamivudine Tablets was prescribed for you. If you know you have this gene, tell your doctor.

#### **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, Dolutegravir Lamivudine Tablets, 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 aches and pains, or generally feeling ill.

Your doctor may advise you to stop taking Abacavir, Dolutegravir Lamivudine Tablets.

#### If you have stopped taking Abacavir, Dolutegravir Lamivudine Tablets

If you have stopped taking Abacavir, Dolutegravir Lamivudine Tablets because of a hypersensitivity reaction, **you must NEVER AGAIN take Abacavir, Dolutegravir Lamivudine Tablets, or any other medicine containing abacavir.** If you do, within hours, your blood pressure could fall dangerously low, which could result in death. You should also never again take medicines containing dolutegravir.

If you have stopped taking Abacavir, Dolutegravir Lamivudine Tablets 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, Dolutegravir Lamivudine Tablets, or any other medicine containing abacavir.** You may also be told never again to take any other medicine containing dolutegravir. 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, Dolutegravir Lamivudine Tablets 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, Dolutegravir Lamivudine Tablets, return all your unused Abacavir, Dolutegravir Lamivudine Tablets tablets for safe disposal. Ask your doctor or pharmacist for advice.

The Abacavir, Dolutegravir Lamivudine Tablets 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.

#### Very common side effects

These may affect more than 1 in 10 people:

- headache
- diarrhoea
- feeling sick (nausea)
- difficulty in sleeping (insomnia)
- lack of energy (fatigue)

#### Common side effects

These may affect up to 1 in 10 people:

- hypersensitivity reaction (see 'Hypersensitivity reactions' earlier in this section)
- loss of appetite
- rash
- itching (pruritus)
- being sick (vomiting)
- stomach (abdominal) pain
- stomach (abdominal) discomfort
- indigestion
- wind (flatulence)
- dizziness

- abnormal dreams
- nightmares
- depression (feelings of deep sadness and unworthiness)
- tiredness
- fever (high temperature)
- cough
- irritated or runny nose
- hair loss
- muscle pain and discomfort
- joint pain
- feeling weak
- general feeling of being unwell

Common side effects that may show up in blood tests are:

- an increase in the level of liver enzymes

#### Uncommon side effects

These may affect up to 1 in 100 people:

- inflammation of the liver (hepatitis)
- suicidal thoughts and behaviours (particularly in patients who have had depression or mental health problems before)

Uncommon side effects that may show up in blood tests are:

- a decreased number of cells involved in blood clotting (thrombocytopenia).
- a low red blood cell count (anaemia) or low white blood cell count (neutropenia)
- an increase in sugar (glucose) in the blood
- an increase in triglycerides (type of fat) in the blood

#### Rare side effects

These may affect up to 1 in 1000 people:

- 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).

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 any side effects

→ **Talk to your doctor.** This includes any possible side effects not listed in this leaflet.

Other possible side effects of combination therapy for HIV

Combination therapy such as Abacavir, Dolutegravir Lamivudine Tablets may cause other conditions to develop during HIV treatment.

#### Symptoms of infection and inflammation

People with advanced HIV infection or 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.** Don't take other medicines for the infection without your doctor's advice

Joint pain, stiffness and bone problems

Some people taking combination therapy for HIV develop a condition called *osteonecrosis*. In 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, please report it immediately via following e-mail address: [pharmacovigilance@aurobindo.com](mailto:pharmacovigilance@aurobindo.com)". By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Abacavir, Dolutegravir Lamivudine Tablets**

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

- Do not store above 30°C. Store in the original package.
- Keep Abacavir, Dolutegravir Lamivudine Tablets in the original container.
- Do not use Abacavir, Dolutegravir Lamivudine Tablets if the seal over the bottle opening is broken or missing.
- Keep the bottle tightly closed. Protect from moisture.
- The bottle contains a desiccant packet to help keep your medicine dry (protect it from moisture). Keep the desiccant packet in the bottle. Do not remove the desiccant packet.

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. Further information**

**What Abacavir, Dolutegravir Lamivudine Tablets contains**

- The active substances are Abacavir, Dolutegravir and Lamivudine.

Each film-coated tablet contains Abacavir sulfate USP equivalent to 600 mg of abacavir, Dolutegravir sodium equivalent to dolutegravir 50 mg and Lamivudine USP 300 mg.

- The other ingredients in the tablet core are Microcrystalline cellulose, mannitol, sodium starch glycolate, povidone, magnesium stearate.

- The other ingredients in the tablet film coating are Macrogol/polyethylene glycol, polyvinyl alcohol, talc and titanium dioxide.

**What Abacavir, Dolutegravir Lamivudine Tablets looks like and contents of the pack**

Abacavir, Dolutegravir and Lamivudine Tablets are White to off white, oval shaped, biconvex, film-coated tablets and debossed with "N" on one side and with "17" on other side.

The film-coated tablets are provided in bottles containing 30 & 90 tablets.