

## PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

### Abacavir and Lamivudine Tablets USP, 600 mg/300 mg

{Abacavir Sulfate & Lamivudine}

#### Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- 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 health care provider. This includes any possible side effects not listed in this leaflet..

#### **HYPERSENSITIVITY REACTION**

Patients taking Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets may develop a hypersensitivity reaction (serious allergic reaction) to abacavir, which **can be life-threatening** if treatment with Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets is continued. It is essential you read the information on this reaction under "Warnings and precautions" of this leaflet.

**CONTACT YOUR HEALTH CARE PROVIDER IMMEDIATELY for advice on whether you should stop taking Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets if:**

**1) You get a skin rash OR**

**2) You get one or more symptoms from at least TWO of the following groups**

- fever
- shortness of breath, sore throat or cough
- nausea or vomiting or diarrhoea or abdominal pain
- severe tiredness or achiness or generally feeling ill

If you have discontinued Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets due to a hypersensitivity reaction, **YOU MUST NEVER TAKE** Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets or any other medicine containing abacavir again, as **within hours** you may experience a life-threatening lowering of blood pressure or death.

#### **In this leaflet:**

1. What Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets is and what it is used for
2. What you need to know before you take Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets
3. How to take Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets
4. Possible side effects
5. How to store Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets
6. Further information

## **1. WHAT ABACAVIR (AS SULFATE)/ LAMIVUDINE 600MG/300MG TABLETS IS AND WHAT IT IS USED FOR:**

Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets is a combination product containing abacavir and lamivudine. Both these drugs belong to a group of antiviral medicines, also known as antiretrovirals, called nucleoside analogue reverse transcriptase inhibitors (NRTIs). These are used to treat Human Immunodeficiency Virus (HIV) infection.

Abacavir and lamivudine are used in combination with other antiretroviral medicines for the treatment of HIV infection. They reduce the amount of HIV in your body, and keep it at a low level. They also increase CD4 cell counts. CD4 cells are a type of white blood cell that plays an important role in maintaining a healthy immune system to help fight infection. Response to treatment with abacavir and lamivudine varies between patients. Your health care provider will be monitoring the effectiveness of the treatment.

## **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ABACAVIR (AS SULFATE)/ LAMIVUDINE 600MG/300MG TABLETS**

### **You should not take Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets if:**

you are allergic (hypersensitive) to the active substances abacavir (or any other medicine containing Abacavir), lamivudine or any of the other ingredients of this medicine

### **Warnings and precautions**

It is important that your health care provider knows about all symptoms even when you think they are not related to HIV infection.

#### *Hypersensitivity reaction (serious allergic reaction)*

About 5 in every 100 patients, who were treated with abacavir, developed a hypersensitivity reaction to the active ingredient abacavir. People with a genetic variant called HLA-B\*5701 are more likely to have a hypersensitivity reaction to abacavir. If you know you have this gene variant, be sure to tell your health care provider. However, even if you do not have this gene variant it is still possible to get this reaction. About 3 to 4 in every 100 patients treated with abacavir in a clinical trial who did not have a gene called HLA-B\*5701 developed a hypersensitivity reaction (a serious allergic reaction).

The most common symptoms of the abacavir hypersensitivity reaction are fever and a skin rash.

Other frequently observed signs or symptoms include nausea, vomiting, diarrhoea, abdominal pain and severe tiredness. Other symptoms may include joint or muscle pain, swelling of the neck, shortness of breath, sore throat, cough and headache. Occasionally, inflammation of the eye (conjunctivitis), mouth ulcers or low blood pressure may occur. The symptoms of this allergic reaction can occur at any time during treatment with Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets. However, if they occur, this usually happens within the first six weeks of treatment. The symptoms worsen with continued treatment and may be lifethreatening if treatment is continued.

**CONTACT YOUR HEALTH CARE PROVIDER IMMEDIATELY for advice on whether you should stop Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets if:**

**1) you get a skin rash OR**

**2) you get one or more symptoms from at least TWO of the following groups**

-fever

-shortness of breath, sore throat or cough

-nausea or vomiting or diarrhoea or abdominal pain

-severe tiredness or achiness or generally feeling ill.

If you have discontinued Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets due to a hypersensitivity reaction, **YOU MUST NEVER TAKE** Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets or any other medicine containing abacavir again, as **within hours** there may be a life-threatening lowering of blood pressure or death.

If you have stopped taking Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets for any reason, particularly because of side effects or other illness, it is important that you contact your healthcare provider before restarting. Your healthcare provider will check whether any symptoms may be related to this hypersensitivity reaction. If your healthcare provider thinks there is a possibility that they were related, you will be instructed **never to take** Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets **or any other medicine containing abacavir again**. It is important that you follow this advice.

Occasionally life-threatening hypersensitivity reactions have occurred when abacavir was restarted in patients who reported **only one** of the symptoms on the Alert Card before stopping. On very rare occasions hypersensitivity has been reported when abacavir was restarted in patients who had **no symptoms** of hypersensitivity before stopping. If you are hypersensitive to abacavir you should return all the unused Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets for disposal. Ask your healthcare provider for advice.

#### *Kidney disease*

Before you use Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets, you should have told your health care provider if you are suffering from or have ever suffered from kidney disease. If so, the dose of Lamivudine may need to be reduced. In such cases other formulations of Abacavir and Lamivudine than Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets should be used.

#### *Liver disease*

Before you use Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets, you should have told your health care provider if you have or ever had a liver disease (such as hepatitis). Patients with chronic hepatitis B or C and treated with antiretroviral agents are at increased risk for severe and potentially fatal liver adverse events and may require blood tests to monitor liver function. If you have chronic hepatitis B infection, you should not stop treatment without instructions from your healthcare provider,

#### *Lactic acidosis*

Females, particularly if very overweight, and patients with liver disease may be more at risk of getting a rare, but serious side effect called lactic acidosis, a build up of lactic acid in the body. If lactic acidosis occurs, it usually develops after a few months of treatment. Deep rapid breathing, drowsiness and non-specific symptoms such as nausea, vomiting and stomach pain, might indicate the development of this condition. While you are being treated with Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets your health care provider will monitor for any signs of lactic acidosis.

#### *Immune Reactivation Syndrome*

In some patients with advanced HIV infection (AIDS) and a history of opportunistic infections, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present previously with no obvious symptoms. If you notice any symptoms of infection, inform the healthcare provider immediately. 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.

#### *Bone problems*

Some patients taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue). The risk of developing this disease may be higher, e.g. when the immune system is severely compromised or when drinking alcohol regularly. So far, this disease has been reported mainly in adults. However, if you notice joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement, inform your health care provider.

#### *Heart attack*

It cannot be excluded that abacavir might be associated with an increased risk of heart attack. If you have heart problems, you smoke or you suffer from diseases that increase the risk of heart disease such as high blood pressure and diabetes, your health care provider should be informed.

#### *General*

You will need to take Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets every day. This medicine helps to control the condition, but it is not a cure for HIV infection. You may continue to develop other infections and other illnesses associated with HIV disease (e.g. opportunistic infections). These will require specific and sometimes preventive treatment. You should keep in regular contact with your health care provider. Do not stop the medicine without first talking to your health care provider.

#### *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 health care provider the precautions needed to avoid infecting other people.

#### **Other medicines and Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets**

Please tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. The amount of abacavir in your blood may be altered by the concomitant use with:

- alcohol
- oral vitamin A related medicines, e.g. isotretinoin (for acne therapy)
- rifampicin (medicine for treatment of tuberculosis)
- phenobarbital and phenytoin (medicines for treatment of seizures)
- lopinavir with ritonavir, tipranavir with ritonavir (other antiretroviral medicines)

As abacavir increases the rate at which methadone, a heroin substitute, is removed from the body, patients taking methadone will be checked for any withdrawal symptoms, and may have their methadone dose changed. Lamivudine should not be used in combination with

- emtricitabine (other antiretroviral medicine)
- other medicinal products containing lamivudine, used to treat HIV infection or hepatitis B infection
- high dose co-trimoxazole (antibiotic).
- cladribine, used to treat hairy cell leukaemia

#### **Taking Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets with food and drink**

Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets can be taken with or without food.

#### **Pregnancy and breast-feeding**

If you become pregnant, or are planning to become pregnant, you must contact your health care provider to discuss the potential benefits and risks of your antiretroviral therapy to you and your child.

If you have taken abacavir/lamivudine during your pregnancy, your health care provider may request regular visits to monitor the development of your child. Such visits may include blood tests and other diagnostic tests.

In children whose mothers took nucleoside and nucleotide analogues during pregnancy, the benefit of the reduced risk of being infected with HIV is greater than the risk of suffering from side effects.

If you are interested in breast-feeding your baby, you should discuss the risks and benefits with your health care provider.

### **Driving and using machines**

No studies on the effects of abacavir on the ability to drive and use machines have been performed. However, you should take into account the state of your health and the possible side effects of abacavir and lamivudine before considering driving or using machines.

### **3. HOW TO TAKE ABACAVIR (AS SULFATE)/ LAMIVUDINE 600MG/300MG TABLETS**

Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets should be taken exactly as described by your healthcare provider. You should check with your health care provider if you are not sure.

Adults, adolescents and children weighing at least 25 kg:

The recommended dose of Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets is one tablet once daily.

Children under 25 kg:

Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets should not be administered to children who weigh less than 25 kg because appropriate dose adjustments cannot be achieved with this product. Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets can be taken with or without food.

#### **If one takes more Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets than one should**

If you accidentally take too much medicine you should tell your health care provider, or contact your nearest hospital emergency department for further advice.

#### **If you forget to take Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets**

It is important not to miss doses of Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets. If you forget to take a dose of your medicine, and notice this within 6 hours, take the missed dose as soon as possible. Take the next regular dose as scheduled. If you notice this later, take the normal dose when the next one is due. Do not take a double dose to make up for the forgotten individual doses. It is important to take Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets regularly, because irregular dosing may increase the risk of hypersensitivity reactions.

#### **If one stops taking Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets**

Because this medicine controls and does not cure your condition, you will normally need to take it continuously. You should not stop treatment unless your health care provider tells you to. If you have any further questions on the use of this product, ask your health care provider.

### **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 health care provider will test for these changes.

Like all medicines, Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets can cause side effects, although not everybody gets them. When treating HIV infection, it is not always possible to tell whether

some of the undesirable effects that occur are caused by Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets, by other medicines being taken at the same time, or by the HIV disease. For this reason it is very important that you inform your health care provider about any changes in your health.

**A hypersensitivity reaction (serious allergic reaction) has been reported in about 5 in every 100 patients who have been treated with abacavir.** This is described under “Warnings and precautions” in section 2 of this leaflet. It is important that you read and understand the information about this serious reaction.

The following list of side effects is mainly based on data from adult patients.

**Common side effects** (these can affect at least 1 in every 100 patients treated, but less than 1 in every 10 patients treated):

- hypersensitivity reaction
- anorexia
- skin rash (without any other illness)
- nausea, vomiting, diarrhea, stomach pain
- headache, insomnia, dizziness
- cough, nasal symptoms (irritation, runny nose)
- fever
- muscle pain and discomfort
- joint pain
- hair loss
- tiredness, fatigue, loss of appetite
- difficulty in sleeping (insomnia)

**Uncommon side effects** (these can affect at least 1 in every 1000 patients treated, but less than 1 in every 100 patients treated):

- anaemia (low red blood cell count), neutropenia (low white blood cell count), and reductions in platelets (blood cells important for blood clotting). If the number of red blood cells is reduced one may have symptoms of tiredness or breathlessness. A reduction in white blood cell count can make you more prone to infection. If you have a low platelet count one may notice that he/she bruises more easily.
- increases in the blood levels of some liver enzymes.

**Rare side effects** (these can affect at least 1 in every 10 000 patients treated, but less than 1 in every 1000 patients treated):

- inflammation of the pancreas (pancreatitis)
- inflammation of the liver (hepatitis)
- breakdown of muscle tissue

- rise in serum amylase

**Very rare side effects** (these can affect less than 1 in every 10 000 patients treated):

- 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*).
- pure red cell aplasia (a type of anaemia affecting the precursors to red blood cells but not to white blood cells.)

lactic acidosis (a build up of lactic acid in the body, that can cause dehydration and coma).

Deep, rapid breathing, drowsiness, and non specific symptoms such as nausea, vomiting and stomach pain, may indicate the development of lactic acidosis.

- peripheral neuropathy

**Frequency not known:**

The following side effects have been reported in patients treated with medicines of the group of NRTIs, to which also abacavir and lamivudine belong. However, frequency estimates for these effects are not available:

- osteonecrosis (death of bone tissue)
- immune reactivation syndrome and autoimmune disorders

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your healthcare provider .

## 5. HOW TO STORE ABACAVIR (AS SULFATE)/LAMIVUDINE 600MG/300MG TABLETS

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

Do not store above 30°C. Store in the original container.

Do not use this medicine after the expiry date which is stated on the 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. FURTHER INFORMATION

### CONTENTS OF THE PACK AND OTHER INFORMATION

#### What Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets contains

The active ingredients are 600 mg Abacavir (as sulfate) and 300 mg Lamivudine.

The other ingredients are: Microcrystalline cellulose, Sodium starch glycolate Type A, Povidone, Colloidal silicon dioxide, Low-substituted hydroxypropyl cellulose, Magnesium stearate, Instacoat



Abacavir and Lamivudine WHO Prequalification Team: December 2018  
Tablets USP, 600 mg/300 mg medicines — WHOPAR part 3  
universal orange A05G32713(HPMC 2910/Hypromellose, Polyethylene Glycol, Polysorbate 80,  
Titanium Dioxide, FD&C Yellow No. 6 Al. Lake).

**What Abacavir (as sulfate)/Lamivudine 600mg/300mg Tablets looks like and contents of the pack**

Orange colored, modified capsule shaped, biconvex film coated tablets debossed with "I 60" on one side and plain on other side.

**Container Pack:** Round, white, HDPE, 75 CC HW, 38 mm neck finish container with 38 mm Child resistant closure with pulp and HS white printed liner along with 1 gm carbon/silica blend sachet (One Pillow pack per container).

Container pack of 30's Tablets along with pack insert.

**Supplier**

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**This leaflet was last approved on {MM/YYYY}.**

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