PATIENT INFORMATION LEAFLET

Please read all of this leaflet carefully before you start taking ADCO-ABACAVIR TABLETS, even if you have just refilled your prescription or used ADCO-ABACAVIR TABLETS before. Some of the information in the previous leaflet may have changed. Remember that your doctor has prescribed ADCO-ABACAVIR TABLETS only for you. Never give it to anyone else.

SCHEDULING STATUS: S4
PROPRIETARY NAME (AND DOSAGE FORM): ADCO-ABACAVIR TABLETS (FILM-COATED TABLETS)

HYPERSENSITIVITY REACTION
Patients taking ADCO-ABACAVIR TABLETS may develop a hypersensitivity reaction (serious allergic reaction) which may be life-threatening if treatment with ADCO-ABACAVIR TABLETS is continued. It is essential that you read the information on this reaction under "Take special care with ADCO-ABACAVIR TABLETS in this leaflet. There is also an Alert Card included in the ADCO-ABACAVIR TABLETS pack, to remind you and medical staff about ADCO-ABACAVIR TABLETS hypersensitivity. This card should be removed and kept with you at all times.
CONTACT YOUR DOCTOR IMMEDIATELY for advice on whether you should stop taking ADCO-ABACAVIR 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 ADCO-ABACAVIR TABLETS due to a hypersensitivity reaction, YOU MUST NEVER TAKE ADCO-ABACAVIR TABLETS, or any other medicine containing abacavir again, as within hours you may experience a life-threatening lowering of your blood pressure or death.

WHAT ADCO-ABACAVIR TABLETS CONTAINS:

Each tablet contains the equivalent of 300 mg abacavir as abacavir sulphate.
The other ingredients in the tablet are:
Microcrystalline cellulose pH102
Sodium starch glycolate
Colloidal silicone dioxide
Magnesium stearate
Colour Opadry II green 85F21779

WHAT ADCO-ABACAVIR TABLETS IS USED FOR:

ADCO-ABACAVIR TABLETS belongs to a group of antiviral medicines. These are used to treat Human Immunodeficiency Virus (HIV) infection.
ADCO-ABACAVIR TABLETS is used in combination with other antiretroviral medicines in the treatment of HIV infection in adults and children older than 12 years of age.

Date of Approval: 10 June 2010

BEFORE TAKING ADCO-ABACAVIR TABLETS:

ADCO-ABACAVIR TABLETS is not a cure for HIV infection or AIDS. Patients taking **ADCO-ABACAVIR TABLETS** may still develop infections or other illnesses associated with HIV disease and AIDS. It is therefore important that you remain under the supervision of your doctor while taking **ADCO-ABACAVIR TABLETS**. **ADCO-ABACAVIR TABLETS** does not reduce the risk of passing HIV to others through sexual contact or blood contamination. You should use appropriate precautions.

Do not take this medicine in the following cases:

- If you have ever had an allergic reaction to abacavir (**ADCO-ABACAVIR TABLETS**) or any of the other ingredients in these tablets.
- If you have liver disease, you should not take **ADCO-ABACAVIR TABLETS**.
- If you are pregnant or breast-feeding your baby.
- **ADCO-ABACAVIR TABLETS** must not be used in children under the age of 12.

Take special care with ADCO-ABACAVIR TABLETS for the following reasons:

ADCO-ABACAVIR TABLETS may lead to serious problems with your liver or cause too much acid in your blood. If left untreated, this may even cause death. The safety and efficacy of ADCO-ABACAVIR TABLETS in patients who are infected with both human immunodeficiency virus (HIV) and hepatitis B virus (HBV) have not been established. ADCO-ABACAVIR TABLETS should not be used for the treatment of chronic HBV infection. You should be closely monitored by your doctor for several months if you are infected with HBV and discontinue the use of ADCO-ABACAVIR TABLETS.

Hypersensitivity reaction (serious allergic reaction): Patients treated with abacavir may develop a hypersensitivity reaction. (See boxed warning at the beginning of the Patient Information Leaflet). Research has found that people with the gene HLA-B*5701 are more likely to have a hypersensitivity reaction to abacavir. However, even if you do not have this gene type, it is possible for you to get this reaction, which could be life-threatening if you continue to take ADCO-ABACAVIR TABLETS.

If you know you have this gene type, be sure to tell your doctor before you take ADCO-ABACAVIR TABLETS.

The most common symptoms of this reaction are high temperature (fever) and a skin rash. Other frequently observed signs are 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 **ADCO-ABACAVIR TABLETS**. However they usually occur in the first six weeks of treatment. The symptoms worsen with continued treatment and may be life-threatening if treatment is continued. If you are caring for a child who is being treated with ADCO-ABACAVIR TABLETS, it is important that you understand the information about this hypersensitivity

reaction. If your child gets the symptoms described below it is essential that you follow the instructions given.
CONTACT YOUR DOCTOR IMMEDIATELY for advice on whether you should stop taking ADCO-ABACAVIR 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 **ADCO-ABACAVIR TABLETS** due to a hypersensitivity reaction, YOU MUST NEVER TAKE **ADCO-ABACAVIR TABLETS** or any other medicine containing abacavir again, as within hours you may experience a life-threatening lowering of your blood pressure or death.
If you have stopped taking **ADCO-ABACAVIR TABLETS** for any reason, particularly because you think you are having side effects or for other illness, it is important that you contact your doctor before restarting. Your doctor will check whether any symptoms you had may be related to this hypersensitivity reaction. If your doctor thinks there is a possibility that they were related, you will be instructed never to take **ADCO-ABACAVIR TABLETS** or any other medicine containing abacavir again. It is important that you follow this advice.
Occasionally life-threatening hypersensitivity reactions have occurred when **ADCO-ABACAVIR TABLETS** 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 **ADCO-ABACAVIR TABLETS** was restarted in patients who had no symptoms of hypersensitivity before stopping.
If you are hypersensitive to **ADCO-ABACAVIR TABLETS** you should return all of your unused **ADCO-ABACAVIR TABLETS** for disposal. Ask your doctor or pharmacist for advice.

- **ADCO-ABACAVIR TABLETS** can cause a life-threatening and fatal allergic reaction. If you experience any symptoms (see boxed warning above), contact your doctor immediately. If an allergic reaction is confirmed, you must never take **ADCO-ABACAVIR TABLETS** again. Please note that not taking **ADCO-ABACAVIR TABLETS** regularly may increase the risk of you having an allergic reaction. You must take **ADCO-ABACAVIR TABLETS** regularly.
- If you have liver disease, avoid using **ADCO-ABACAVIR TABLETS** as it may make it worse.
- If you suffer from severe kidney disease, you should avoid using **ADCO-ABACAVIR TABLETS**.

Pregnancy and breast-feeding

- Pregnancy: **ADCO-ABACAVIR TABLETS** has not been studied in pregnant women. However, animal studies showed that **ADCO-ABACAVIR TABLETS** can cause birth defects. Before taking **ADCO-ABACAVIR TABLETS** make sure your doctor knows if you are pregnant or if you may become pregnant.

"If you are pregnant or breast-feeding your baby while taking ADCO-ABACAVIR TABLETS, please consult your doctor, pharmacist or other healthcare professional for advice."

- Breast-feeding: **ADCO-ABACAVIR TABLETS** has not been shown to be safe during breast-feeding. Mothers taking **ADCO-ABACAVIR TABLETS** should not breast-feed their infants.

Taking other medicines with ADCO-ABACAVIR TABLETS:
Alcohol may decrease the elimination of **ADCO-ABACAVIR TABLETS**, causing an increase in the blood concentrations of **ADCO-ABACAVIR TABLETS**.

"If you are taking other medicines on a regular basis, concomitant use of ADCO-ABACAVIR TABLETS may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice."

HOW TO TAKE ADCO-ABACAVIR TABLETS:
Do not share medicines prescribed for you with other persons.
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the hospital or poison control center.
It is important that you take ADCO-ABACAVIR TABLETS exactly as directed by your doctor.
Do not take it more often and do not take it for a longer time than your doctor ordered. If you miss a dose, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses. Even if you feel better, do not stop taking **ADCO-ABACAVIR TABLETS** without talking to your doctor. This medicine must be taken in combination with other antiretrovirals.
ADCO-ABACAVIR TABLETS can be taken with or without food.
Adults and children older than 12 years: the recommended dose of **ADCO-ABACAVIR TABLETS is 300 mg (one tablet twice daily)** with a maximum daily dose of 600 mg.
Therapy should be initiated by a physician experienced in the management of HIV infection.

If you take more ADCO-ABACAVIR TABLETS than you should
If you accidentally take too much of **ADCO-ABACAVIR TABLETS** you should tell your doctor or your pharmacist, or contact your nearest hospital emergency department for further advice.

If you forget to take ADCO-ABACAVIR TABLETS
If you forget to take a dose of **ADCO-ABACAVIR TABLETS**, take it as soon as you remember, and then continue as before. Do not take a double dose to make up for a forgotten dose. It is important to take **ADCO-ABACAVIR TABLETS** regularly because irregular intake may increase the risk of hypersensitivity reactions.

If you stop taking ADCO-ABACAVIR TABLETS
If you have stopped taking **ADCO-ABACAVIR TABLETS** for any reason, particularly because you think you are having side effects or for other illness, it is important that you contact your

doctor before restarting. In some cases your doctor will ask you to restart **ADCO-ABACAVIR TABLETS** in a place where you will be able to get ready access to medical care if needed.

SIDE EFFECTS:

ADCO-ABACAVIR TABLETS can have side effects.
"Not all side effects reported for ADCO-ABACAVIR TABLETS are included in this leaflet. Should your general health worsen while taking ADCO-ABACAVIR TABLETS, please consult your doctor, pharmacist or other healthcare professional for advice."

Check with your doctor IMMEDIATELY if you think you're experiencing an allergic reaction.

Allergic reaction:
Severe allergic reactions, sometimes fatal, have occurred in about some patients taking **ADCO-ABACAVIR TABLETS**, especially (but not exclusively) during the first six weeks of treatment, or during intermittent therapy. Symptoms of an allergic reaction include fever, rash, cough, dyspnoea (difficulty breathing/shortness of breath), lethargy (severe tiredness), malaise (general feeling of illness), headache, muscle pain, and gastrointestinal disturbances, particularly nausea and vomiting, diarrhoea, and abdominal pain. Shock has occurred. Caution is needed as hypersensitivity may be misdiagnosed as the flu, respiratory disease, or gastroenteritis.
This is a serious and potentially life-threatening allergic reaction. *Stop taking* ***ADCO-ABACAVIR TABLETS*** *and report to your doctor or hospital immediately.*

Check with your doctor if you experience any of the following symptoms:
Frequent side effects:
- skin rash,
- nausea, vomiting, diarrhoea,
- headache,
- high temperature,
- lethargy, fatigue, loss of appetite.

Less frequent side effects:
- inflammation of the pancreas (pancreatitis).
- serious skin reactions.

Cases of a condition called lactic acidosis, which is a build-up of lactic acid in the body, that can cause dehydration and coma have been reported on rare occasions in patients taking NRTIs. Combination antiretroviral therapy may cause changes in body shape due to changes in fat distribution. These may include loss of fat from legs, arms and face, increased fat in the abdomen (belly) and other internal organs, breast enlargement and fatty lumps on the back of the neck ('buffalo hump'). The cause and long-term health effects of these conditions are not known at this time. Combination antiretroviral therapy may also cause raised lactic acid and sugar in the blood, hyperlipaemia (increased fats in the blood) and resistance to insulin.

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

STORAGE AND DISPOSAL INFORMATION:

Store at or below 30 °C.
The blisters must be kept in the carton until required for use.
The containers must be tightly closed.
KEEP OUT OF REACH OF CHILDREN.

PRESENTATION:

Securitainer:

56's tablets are packed in a white polypropylene securitainer fitted with a low density polyethylene lid. A white polypropylene capsule containing silica gel desiccant is included in the container.

Blister packs:

60's tablets are packed in blister strips composed of white opaque PVC/PVDC an Aluminium foil or of white opaque PVC/PE/PVDC and Aluminium foil. Four strips containing 15 tablets each are packed on an outer cardboard carton.

IDENTIFICATION:

A blue/grey, oval, film coated, double convex tablet with a break-line on one side.

REGISTRATION NUMBER:

43/20.2.8/0386

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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