

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

ASPEN ABACAVIR 300

Abacavir

Film-coated tablets

Read all of this leaflet carefully before you start taking ASPEN

ABACAVIR 300.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- ASPEN ABACAVIR 300 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SPECIAL WARNING

Patients taking ASPEN ABACAVIR 300 may develop a hypersensitivity reaction (serious allergic reaction) which can be life-threatening and can cause death, if treatment with ASPEN ABACAVIR 300 is continued. It is essential that you read the information on this reaction in the section BEFORE YOU TAKE ASPEN ABACAVIR 300 of this leaflet. There is also an alert card included in the ASPEN ABACAVIR 300 pack to remind you and medical staff about this medicine's hypersensitivity. This card should be

removed from the pack and kept with you at all times. The text on this card is shown below. Patients taking ASPEN ABACAVIR 300 may develop a hypersensitivity reaction (serious allergic reaction) which can be life-threatening if treatment with ASPEN ABCAVIR 300 is continued.

CONTACT YOUR DOCTOR IMMEDIATELY for advice on whether you should stop taking ASPEN ABACAVIR 300 if:

- you get a skin rash OR
- you get one or more symptoms from at least TWO of the following groups:
 - shortness of breath, sore throat or cough
 - nausea and vomiting or diarrhoea or abdominal pain
 - severe tiredness or achiness or general ill feeling

If you have discontinued ASPEN ABACAVIR 300 due to a hypersensitivity reaction **YOU MUST NEVER TAKE** it again, or any other medicine containing abacavir again, as within hours you may experience a life-threatening lowering of your blood pressure or death.

WHAT ASPEN ABACAVIR 300 CONTAINS

The active substance is abacavir.

Each tablet contains 300 mg abacavir.

The other ingredients are colloidal silicon dioxide, hypromellose, iron oxide yellow (C.I. no. 77492), macrogol, magnesium stearate, microcrystalline cellulose (PH-200), sodium starch glycollate (type A), titanium dioxide (C.I. no. 77891).

Sugar free

WHAT ASPEN ABACAVIR 300 IS USED FOR

ASPEN ABACAVIR 300 belongs 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. ASPEN ABACAVIR 300 is used in combination with other antiretroviral medicines for the treatment of HIV infection.

BEFORE YOU TAKE ASPEN ABACAVIR 300

Do not take ASPEN ABACAVIR 300:

- If you have previously suffered an allergic reaction to ASPEN ABACAVIR 300 or to the active ingredient abacavir.
- If you are hypersensitive (allergic) to abacavir or any of the other ingredients in ASPEN ABACAVIR 300.
- If you have liver disease.
- If you are pregnant or breast feeding your baby.

Take special care with ASPEN ABACAVIR 300

Hypersensitivity reaction (serious allergic reaction): The most important symptoms of this reaction are high temperature (fever) and a skin rash. Other frequently seen signs or symptoms are nausea, vomiting, diarrhoea, abdominal pain, shortness of breath, cough, headache, and severe tiredness. Other symptoms may be joint or muscle pain, swelling of the neck and sore throat. Occasionally swelling of the eye (conjunctivitis), ulcers in the mouth or low blood pressure may occur. The symptoms of this allergic reaction can occur at

any time during treatment with ASPEN ABACAVIR 300. However they usually occur in the first six weeks of treatment and get worse with continued treatment.

The hypersensitivity reaction can be life-threatening or fatal if treatment with ASPEN ABACAVIR 300 is continued. You should contact your doctor immediately for advice on whether you should stop taking ASPEN ABACAVIR 300 if:

- you get a skin rash OR
- 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 general ill feeling.

If you have discontinued ASPEN ABACAVIR 300 because of a hypersensitivity reaction YOU MUST NEVER TAKE ASPEN ABACAVIR 300 or any other medicine containing abacavir again as within hours you may experience a life-threatening lowering of your blood pressure or death.

Occasionally life-threatening hypersensitivity reactions have occurred when ASPEN ABACAVIR 300 was restarted in patients who got only one of the symptoms on the alert card before stopping.

If you are hypersensitive to this medicine you should return all unused tablets to your doctor or pharmacist for proper disposal.

Your risk of this allergic reaction is much higher if you have a gene variation called HLA-B*5701 than if you do not. Your doctor can determine with a blood test if you have this gene variation.

ASPEN ABACAVIR 300 can cause a condition called lactic acidosis, together with an enlarged liver. This rare but serious side-effect occurs more often in women. If you have liver disease you may also be more at risk of getting this condition while you are being treated with ASPEN ABACAVIR 300. Your doctor will monitor you for any signs that you may be developing lactic acidosis. ASPEN ABACAVIR 300 helps to control your condition but is not a cure for HIV infection. You will need to take it every day.

Do not stop ASPEN ABACAVIR 300 without first talking to your doctor. If you are concerned that you may be developing symptoms of a hypersensitivity reaction, (see above), call your doctor immediately who will advise you whether you need to stop taking ASPEN ABACAVIR 300. You may continue to develop other infections and other illnesses associated with HIV disease. You should therefore keep in regular contact with your doctor while taking ASPEN ABACAVIR 300.

Treatment with ASPEN ABACAVIR 300 has not been shown to decrease the risk of passing HIV infection on to others by sexual contact or by blood transfer. You should continue to use appropriate precautions to prevent this. This is also applicable to patients with hepatitis B or C co-infection.

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 ASPEN ABACAVIR 300. Discuss with your doctor the precautions needed to avoid

infecting other people.

Some people taking ASPEN ABACAVIR 300 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 are seriously overweight (especially if you are a woman).
- if you are diabetic and using insulin.
- if you have severe kidney disease.

Talk to your doctor if any of these apply to you. You may need extra check-ups, including blood tests, while you are taking your ASPEN ABACAVIR 300.

Tell your doctor if you have any history of heart problems, if you smoke, or have other illnesses that may increase your risk of heart disease such as high blood pressure, high cholesterol, or diabetes. Do not stop taking ASPEN ABACAVIR 300 unless your doctor advises you to do so.

Bone destruction (osteonecrosis) has been reported particularly in patients with advanced HIV-disease and/or long-term exposure to combination antiretroviral therapy. Please see your doctor if you experience joint aches and pain, joint stiffness or difficulty in movement.

Pancreatitis has been observed in some patients receiving ASPEN ABACAVIR 300.

Pancreatitis may present with abdominal pain, nausea, vomiting or elevated biochemical markers. Tell your doctor or pharmacist immediately so the necessary tests may be done.

ASPEN ABACAVIR 300 should not be administered to patients with end stage renal disease.

Tell your doctor if you have any renal conditions.

Inform your doctor or pharmacist if you are using triple combination ARV (nucleoside) treatment. Resistance may occur when abacavir is combined with tenofovir disoproxil fumarate and lamivudine as a once daily regimen.

Use of ASPEN ABACAVIR 300 has been known to cause mitochondrial damage. This affects specific blood cells in the body and can present with anaemia (tiredness), neutropenia (low blood cell count). Inform your doctor or pharmacist if you experience or feel any signs or symptoms.

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 ASPEN ABACAVIR 300.

Taking ASPEN ABACAVIR 300 with food and drink

You can take ASPEN ABACAVIR 300 with or without food.

Alcohol should not be taken with ASPEN ABACAVIR 300 as it increases the amount of abacavir in your blood.

Pregnancy and breastfeeding

You should not take ASPEN ABACAVIR 300 if you are pregnant or breastfeeding your baby.

Pregnancy

ASPEN ABACAVIR 300 is contraindicated (see BEFORE YOU TAKE ASPEN ABACAVIR 300).

You should not take ASPEN ABACAVIR 300 if you are pregnant.

The safe use of this medicine in human pregnancy has not been established. Your doctor will advise whether you should continue to take ASPEN ABACAVIR 300.

Breastfeeding

After taking ASPEN ABACAVIR 300, the active ingredient, abacavir is likely to be found in human breast milk. You are therefore advised not to breastfeed while taking ASPEN ABACAVIR 300.

If you are pregnant or breastfeeding, please consult your doctor, pharmacist or other healthcare professional for advice before taking ASPEN ABACAVIR 300.

Driving and using machinery

Since adverse reactions such as headache, migraine and lack of energy have been reported in patients receiving ASPEN ABACAVIR 300, you should not drive, use machinery or perform any task that require concentration, until you are certain that ASPEN ABACAVIR 300 does not adversely affect your ability to do so (see POSSIBLE SIDE EFFECTS).

Taking other medicines with ASPEN ABACAVIR 300

Always tell your healthcare professional if you are taking any other medicines (this includes complementary or traditional medicines).

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

- Antibiotics such as rifampicin.
- ASPEN ABACAVIR 300 with tenofovir disoproxil fumarate and lamivudine.
- Medication with the substances - lamivudine and/or zidovudine.

- Phenytoin, phenobarbitone for treating epilepsy. Your doctor may need to monitor you while you are taking ASPEN ABACAVIR 300.
- Methadone used as a heroin substitute. ASPEN ABACAVIR 300 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.
- Ribavirin for treating hepatitis C. ASPEN ABACAVIR 300 may make the combination of ribavirin and pegylated interferon less effective at reducing levels of hepatitis C virus in the body.
- Retinoid compounds such as isotretinoin, as this may interact with ASPEN ABACAVIR 300.

HOW TO TAKE ASPEN ABACAVIR 300

Do not share medicines prescribed for you with any other person.

Always take ASPEN ABACAVIR 300 exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose in adults and adolescents over 12 years of age is 300 mg (one tablet) twice daily or 2 x 300 mg (two tablets) once daily.

Take the doses 12 hours apart.

Swallow the tablet whole with water or another drink.

ASPEN ABACAVIR 300 tablets should not be broken.

Your doctor will tell you how long the treatment with ASPEN ABACAVIR 300 will last.

If you have the impression that the effect of ASPEN ABACAVIR 300 is too strong or too weak, talk to your doctor or pharmacist.

If you take more ASPEN ABACAVIR 300 than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the

nearest hospital or poison control centre.

If you forget to take ASPEN ABACAVIR 300

Take your missed dose as soon as you remember, if within a few hours after missing a dose.

Do not take a double dose to make up for forgotten individual doses.

If you have stopped taking ASPEN ABACAVIR 300 for any reason, especially if 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 ASPEN ABACAVIR 300 under direct medical supervision or where medical care can be easily accessed by yourself or others. If your doctor thinks that there is a possibility your symptoms were related to hypersensitivity reaction, you may be told never to take ASPEN ABACAVIR 300 or any other medicine containing abacavir, again.

POSSIBLE SIDE EFFECTS

ASPEN ABACAVIR 300 can have side effects.

Not all side effects reported for ASPEN ABACAVIR 300 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ASPEN ABACAVIR 300, please consult your doctor, pharmacist or other healthcare professional for advice.

It is very important that you inform your doctor about any changes in your health.

A hypersensitivity reaction (serious allergic reaction) has been reported with ASPEN ABACAVIR 300. This is described in the section “SPECIAL WARNINGS” of this leaflet. It is important that you read and understand the information about this serious reaction.

If any of the following occur, stop taking ASPEN ABACAVIR 300 and speak to your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- the side effects described under the 'Take special care with ASPEN ABACAVIR 300' section;
- blistering of the skin, mouth, eyes and genitals and/or abnormal redness of the skin.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ASPEN ABACAVIR 300. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department of your nearest hospital if you notice the following:

- Inflammation of the pancreas, which causes severe pain in the abdomen and back;
- Graves' disease, an autoimmune disease, which causes overproduction of the thyroid hormone, and you feel very anxious and irritable;
- osteonecrosis, when you experience joint aches and pain, joint stiffness or difficulty in movement.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been frequently reported:

- Feeling depressed;
- sleep disturbances;

- abnormal dreams;
- headache;
- migraine (severe headache felt as a throbbing pain at the front or on one side of the head);
- fever;
- chills;
- feeling unwell;
- lack of energy;
- sleepiness;
- anorexia (lack or loss of appetite);
- skin rash (without any signs of illness);
- diarrhoea;
- vomiting;
- nausea.

The following side effects have been reported less frequently:

- Ear, nose and chest infections;
- stomach pain and swelling;
- rhabdomyolysis which is muscle breakdown with symptoms such as muscle weakness, low urine output, fatigue, soreness, bruising, dark, tea-coloured urine, infrequent urination, a fever
- inflammation of the lining of the stomach, characterised by nausea, vomiting and stomach pain (gastritis);
- feeling anxious;
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness;
- reduction in white blood cells which can increase the risk of getting infections;

- changes/irregularities in the liver tests that show how well your liver is working;
- lactic acidosis (build up of lactic acid in your blood);
- severe inflammation of the liver with fat accumulation (steatosis);
- increase in blood sugar level;
- increase in blood fats;
- irregular deposits of fat on the body.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF ASPEN ABACAVIR 300

Store at or below 25 °C.

Protect from light.

Keep in original packaging until required for use.

Do not store in bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF ASPEN ABACAVIR 300

Available in pack sizes of 60 tablets in:

- White, opaque plastic containers (75 ml or 85 ml) with child-resistant, plastic screw closure & layered sealing liner *OR*
- Blister packs of silver aluminium foil and amber plastic film packed into cardboard cartons

Not all packs and pack sizes will necessarily be marketed.

IDENTIFICATION OF ASPEN ABACAVIR 300

A dark-yellow coloured, film-coated biconvex, capsule-shaped tablet, “AB” engraved on one side and break-line on the other side.

REGISTRATION NUMBER

ASPEN ABACAVIR 300: 43/20.2.8/0724

**NAME BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE
CERTIFICATE OF REGISTRATION**

PHARMACARE LIMITED

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DATE OF PUBLICATION

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Date of the most recently revised Patient Information Leaflet: 02 June 2017

(Front of Alert Card):

IMPORTANT ALERT CARD
ASPEN ABACAVIR 300 (Tablets)

Carry this card with you at all times

Patients taking ASPEN ABACAVIR 300 may develop a hypersensitivity reaction (serious allergic reaction) that can be life-threatening if treatment with ASPEN ABACAVIR 300 is continued.

CONTACT YOUR DOCTOR IMMEDIATELY for advice on whether you should stop taking ASPEN ABACAVIR 300 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, cough or sore throat
 - nausea, vomiting, diarrhoea or stomach ache
 - severe tiredness or aches or general ill feeling

If you have discontinued ASPEN ABACAVIR 300 due to this reaction, YOU MUST NEVER take ASPEN ABACAVIR 300 again as within hours you may experience a life-threatening lowering of your blood pressure or death.

Your risk of this allergic reaction is much higher if you have a gene variation called HLA-B*5701 than if you do not. Your doctor can determine with a blood test if you have this gene variation.



(see reverse of card)

(Back of Alert Card):

You should contact your Doctor immediately if you think you are having a hypersensitivity reaction to ASPEN ABACAVIR 300. Write your Doctor's details below:

Doctor: _____ Tel: _____

If your doctor is not available, you must urgently seek alternative medical advice (e.g. the emergency unit of the nearest hospital).

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