PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

ADCO ABACAVIR 20 mg/ml ORAL SOLUTION

Each ml of solution contains the equivalent of 20 mg abacavir as abacavir sulphate.

Read all of this leaflet carefully before you start taking ADCO ABACAVIR SOLUTION

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ADCO ABACAVIR SOLUTION 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.

HYPERSENSITIVITY REACTION

Patients taking ADCO ABACAVIR SOLUTION may develop a hypersensitivity reaction (serious allergic reaction) which may be life-threatening if treatment with ADCO ABACAVIR SOLUTION is continued. It is essential that you read the information on this reaction under "Take special care with ADCO ABACAVIR SOLUTION" in this leaflet. There is also an Alert Card included in the ADCO ABACAVIR SOLUTION pack, to remind you and medical staff about ADCO ABACAVIR SOLUTION 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 SOLUTION 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

DATE OF APPROVAL: 30 JANUARY 2025

PATIENT INFORMATION LEAFLET

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

What is in this leaflet

1. What ADCO-ABACAVIR TABLETS is and what it is used for
2. What you need to know before you use ADCO-ABACAVIR TABLETS
3. How to use ADCO-ABACAVIR TABLETS
4. Possible side effects
5. How to store ADCO-ABACAVIR TABLETS
6. Contents of the pack and other information

1. What ADCO ABACAVIR SOLUTION is and what it is used for

ADCO ABACAVIR SOLUTION contains active substance abacavir sulphate belongs to a group of medicines, known as antiretrovirals. Abacavir sulphate is a nucleoside analogue reverse transcriptase inhibitor. These are used to treat Human Immunodeficiency Virus (HIV) infection.

ADCO ABACAVIR SOLUTION is used in combination with other antiretroviral medicines in the treatment of HIV infection in adults and children. A patient's response to treatment with ADCO ABACAVIR SOLUTION varies. The effectiveness of your treatment will be supervised by your doctor.

2. What you need to know before taking you take ADCO ABACAVIR SOLUTION

Do not take ADCO ABACAVIR SOLUTION:

- If you have had and allergic reaction (hypersensitive) to abacavir or any of the other ingredients of this medicine (listed in Section 6).
- If you have liver disease, you should not take ADCO ABACAVIR SOLUTION.
- If you are pregnant or breast-feeding your baby.

PATIENT INFORMATION LEAFLET

ADCO ABACAVIR SOLUTION is not a cure for HIV infection or AIDS. Patients taking ADCO ABACAVIR SOLUTION 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 this medicine. ADCO ABACAVIR SOLUTION does not reduce
the risk of passing HIV to others through sexual contact or blood contamination. You should
use appropriate precautions.

Warnings and precautions

Take special care with ADCO ABACAVIR SOLUTION

ADCO ABACAVIR SOLUTION 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 SOLUTION in patients who are infected with both human immunodeficiency virus (HIV) and hepatitis B virus (HBV) have not been established. ADCO ABACAVIR SOLUTION 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 SOLUTION.

Hypersensitivity reaction (serious allergic reaction): Patients treated with abacavir who did not have a gene called HLA-8*5701 developed a hypersensitivity reaction. Research has found that people with the gene HLA-8*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 SOLUTION.

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

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 SOLUTION. 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 SOLUTION, 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 SOLUTION if:

1) you get a skin rash OR
2) you get any of the following symptoms:
    - 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 SOLUTION due to a hypersensitivity reaction, YOU MUST NEVER TAKE ADCO ABACAVIR SOLUTION 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 SOLUTION 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 SOLUTION 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 SOLUTION was restarted in patients who reported only one of the symptoms on the Alert Card before stopping. On rare occasions hypersensitivity has been reported when ADCO ABACAVIR SOLUTION was restarted in patients who had no symptoms of hypersensitivity before stopping. Since stopping and restarting ADCO ABACAVIR SOLUTION may increase the risk of hypersensitivity occurring, it is important that you use ADCO ABACAVIR SOLUTION exactly as directed by your doctor and pharmacist and do not stop taking ADCO ABACAVIR SOLUTION without first consulting your doctor.

Please keep the special Alert Card attached to the Package insert with you at all times.

If you are hypersensitive to ADCO ABACAVIR SOLUTION you should return all of your unused ADCO ABACAVIR SOLUTION for disposal. Ask your doctor or pharmacist for advice.

- ADCO ABACAVIR SOLUTION 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 SOLUTION again. Please note that not taking your medicine regularly may increase the risk of you having an allergic reaction. You must take ADCO ABACAVIR SOLUTION regularly.
- If you have liver disease, including hepatitis B or C avoid using ADCO ABACAVIR SOLUTION as it may make it worse. Using ADCO ABACAVIR SOLUTION can result in lactic acidosis which can be fatal. If you experience nausea, vomiting, severe abdominal pain, shortness of breath, fatigue (severe tiredness) and weight loss you must advise your medical practitioner immediately. Treatment with ADCO ABACAVIR SOLUTION will be stopped if the doctor finds clinical or laboratory data that suggests lactic acidosis or toxicity of the liver.
- If you suffer from severe kidney disease, you should avoid using ADCO ABACAVIR SOLUTION.
- If you are seriously overweight (especially if you are a women)
- Abacavir hypersensitivity reactions

- Even patients who don't have the HLA-B*5701 gene may still develop a hypersensitivity reaction (a serious allergic reaction).
- ADCO ABACAVIR SOLUTION is known to cause fat redistribution. You may notice that fat will accumulate around your stomach area, and on your back near your neck, and possibly breast enlargement; you may also notice that fat will disappear from your arms, legs and face. This can be caused by many factors, including HIV disease status (how advanced your HIV is), older age and the duration of antiretroviral treatment. The long term consequences of this fat redistribution are currently unknown. You should alert your doctor to these signs and symptoms of fat redistribution.
- Although you are being treated with ADCO ABACAVIR SOLUTION you may still develop opportunistic infections and other complications of HIV infections. It is therefore important that you visit your clinic regularly for check-up.
- ADCO ABACAVIR SOLUTION does not prevent your risk of transmitting HIV to other people through sexual contact or blood contamination. You are still required to use appropriate precautions.
- Pancreatitis has been observed in some patients taking ADCO ABACAVIR SOLUTION. If you experience abdominal pain, nausea and vomiting you should advise your medical practitioner.
- If you have severe immune deficiency taking ADCO ABACAVIR SOLUTION may develop a syndrome called Immune reconstitution syndrome; whereby the immune system begins to recover, but then responds to a previously acquired opportunistic infection with an overwhelming inflammatory response that results in worse symptoms than previously experienced. This syndrome has been reported during the initial phase of treatment when using a combination of antiretrovirals.
- Whilst taking ADCO ABACAVIR SOLUTION there is a risk of developing osteonecrosis (when the bones die and eventually collapse, leading to pain and arthritis).

  It is most common in the upper leg. Other common sites are your upper arm, knees,

  shoulders and ankles.

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 ADCO ABACAVIR SOLUTION 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 ADCO ABACAVIR SOLUTION.

Read the information 'Other possible side effects of combination therapy for HIV' in Section 4 of this leaflet.

Other medicines and ADCO ABACAVIR SOLUTION:

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

Some medicines interact with ADCO ABACAVIR SOLUTION

These include:

- Alcohol may decrease the elimination of ADCO ABACAVIR SOLUTION, causing an increase in the blood concentrations of ADCO ABACAVIR SOLUTION.
- Phenytoin, for treating epilepsy.

  Tell your doctor if you are taking phenytoin. Your doctor may need to monitor you while you are taking ADCO ABACAVIR SOLUTION.
- 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.

- Riociguat, for treating 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.

ADCO ABACAVIR SOLUTION with food and drink

ADCO ABACAVIR SOLUTION may be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have ~~your~~ baby while taking ADCO-ABACAVIR TABLETS, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Pregnancy:

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

Breast-feeding:

ADCO ABACAVIR SOLUTION has not been shown to be safe during breastfeeding.

Mothers taking ADCO ABACAVIR SOLUTION should not breast-feed their infants.

Driving and using machines

At the moment there is no proof that ADCO ABACAVIR SOLUTION will affect your ability to drive or use machinery.

ADCO ABACAVIR SOLUTION contains sorbitol

ADCO ABACAVIR SOLUTION contains sorbitol which is metabolised to fructose and is therefore unsuitable for patients who have hereditary fructose intolerance.

ADCO ABACAVIR SOLUTION also contains preservatives (parahydroxybenzoates) which may cause allergic reactions (possibly delayed).

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

ADCO ABACAVIR SOLUTION contains 55 mg/ml of propylene glycol. When taken according to the dosage recommendations each 15 ml dose contains approximately 825 mg of propylene glycol.

3. HOW TO TAKE ADCO ABACAVIR SOLUTION

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

Always take ADCO-ABACAVIR exactly as your doctor has instructed told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with ADCO ABACAVIR SOLUTION will last.

Do not stop treatment early because after stopping ADCO ABACAVIR SOLUTION if you need to restart taking it you may develop a life-threatening hypersensitivity reaction.

If you have the impression that the effect of ADCO ABACAVIR SOLUTION is too strong or too weak, tell your doctor or pharmacist.

ADCO ABACAVIR SOLUTION must be taken in combination with other antiretrovirals.

ADCO ABACAVIR SOLUTION can be taken with or without food.

Adults and children over 12 years:

The recommended dose of ADCO ABACAVIR SOLUTION is 600 mg (30 ml) daily.

The oral solution is available for use in children and for those patients in whom the tablet dosage form is inappropriate.

Therapy should be initiated by a doctor experienced in the management of HIV infection.

If you take more ADCO ABACAVIR SOLUTION than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take ADCO ABACAVIR SOLUTION

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

If you stop taking ADCO ABACAVIR SOLUTION

If you have stopped taking ADCO ABACAVIR SOLUTION 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 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 ADCO ABACAVIR SOLUTION, or any other medicine containing abacavir. It is important that you follow this advice. In some cases, your doctor will ask you to restart ADCO ABACAVIR SOLUTION in a place where you will be able to get ready access to medical care if needed.

4. Possible side effects

ADCO ABACAVIR SOLUTION can have side-effects.

Not all side effects reported for ADCO ABACAVIR SOLUTION are included in this leaflet.

Should your general health worsen while taking ADCO ABACAVIR SOLUTION, please consult your healthcare provider for advice.

If any of the following happens, stop taking/using ADCO ABACAVIR SOLUTION and tell your doctor immediately or go to the casualty department at your nearest hospital:

This allergic reaction is severe and may be fatal. Symptoms of this allergic reaction include

- Fever
- rash
- Cough
- Dyspnoea (difficulty breathing/shortness of breath)
- Malaise (general feeling of illness)
- Headache
- Lethargy (severe tiredness)
- Muscle pain, and gastrointestinal disturbances, ~~particularly~~
- Diarrhoea

These are all very serious side effects. If you or your child have them you may have had a serious allergic reaction to ADCO ABACAVIR SOLUTION. You may need urgent medical attention or hospitalisation.

Stop taking ADCO ABACAVIR SOLUTION and call your doctor at once if you notice any of the following:

- Nausea and vomiting
- Abdominal pain and possibly shock.
- Joint pain
- Joint stiffness
- Yellowing of the skin and eyes, dark urine and tiredness
- Anaemia, neutropenia (low count of that are a type of white blood cell), loss of consciousness, difficulty in movement in infants (babies).

These are all serious side effects and may be due to issues in pancreas, liver, degenerative joint disease problem or mitochondrial damage of infants exposed to medicine. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Eating disorder (anorexia)
- High temperature
- Loss of appetite
- Fatigue

Less frequent side effects:

- Inflammation of the pancreas (pancreatitis)
- Serious skin reactions, 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)
- Excess lactic acid in the blood (lactic acidosis)

Frequency not known:

- Severe allergy
- Increase in blood sugar
- Increase fat in the blood

Other possible side effects of combination therapy for HIV

Combination therapy including ADCO ABACAVIR SOLUTION may cause other conditions to develop during HIV treatment.

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 antiretroviral therapies. 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.

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). When these people start treatment, they may find that old, hidden infections flare up, causing signs and symptoms of inflammation.

These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight these infections. 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

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 side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: provide more https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help information on the safety of ADCO ABACAVIR SOLUTION.

5. How to store ADCO ABACAVIR SOLUTION

Store at or below 25 °C.

Keep the bottles tightly closed.

Store all medicines out of reach of children.

Do not store in bathrooms.

Do not use after expiry date on the bottle.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What ADCO ABACAVIR SOLUTION contains:

The active substance in ADCO ABACAVIR SOLUTION is 20 mg of abacavir (as sulfate) in each ml of the solution.

The other ingredients in ADCO ABACAVIR SOLUTION are:

Methyl parahydroxy benzoate, Propyl parahydroxy benzoate, Citric acid, anhydrous (Powder, EMPROVE), Propylene glycol, Purified water, Saccharin sodium, Sodium citrate

Sorbitol, liquid (Noncrystallizing) (Neosorb 70/70B), Strawberry flavour FL N&A WILD TYPE No. 958[4], Banana flavour ART No. 11090 K[4]

What ADCO ABACAVIR SOLUTION looks like and contents of the pack

ADCO ABACAVIR 20 mg/ml ORAL SOLUTION is to clear to opalescent, yellowish, strawberry-banana flavoured liquid.

PRESENTATION OF ADCO ABACAVIR SOLUTION:

250 ml white opaque HDPE bottles with white, ribbed, plastic cap. The bottle is packed in a cardboard carton.

HOLDER OF THE CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, Johannesburg,1685,

PATIENT INFORMATION LEAFLET

Gauteng,

South Africa.

Customer Care: 0860 ADCOCK / 232625

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30 January 2025

REGISTRATION NUMBER (S):

43/20.2.8/0910

Botswana	
Product name	**Registration number**
Adco-Abacavir oral solution	BOT1903603

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