APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

ABDOVIR, 60 mg/5 mg/30 mg tablets for oral suspension.

Abacavir, dolutegravir and lamivudine

Contains sugar: mannitol 14,540 mg.

Contains sweetener: acesulfame potassium 12,000 mg per tablet and sucralose 4,800 mg per tablet.

Read all of this leaflet carefully before you start taking ABDOVIR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.
- ABDOVIR 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:

ABDOVIR contains abacavir. Some people who take abacavir may develop a hypersensitivity reaction (a serious allergic reaction), which can be **life-threatening** if treatment with ABDOVIR is continued.

It is essential you read the information on this reaction under “Warnings and precautions" in section 2 of this leaflet. There is also an Alert Card included in the ABDOVIR pack to remind you and medical staff about abacavir hypersensitivity. This card should be removed and kept with you at all times.

CONTACT YOUR CHILD'S DOCTOR OR HEALTH CARE PROVIDER IMMEDIATELY for advice on whether your child should stop taking ABDOVIR, if:

1. He/she gets a skin rash OR

2. He/she gets 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 your child has stopped staking ABDOVIR due to a hypersensitivity reaction, **HE/SHE MUST NEVER TAKE ABDOVIR** or any other medicine containing abacavir again, as within hours your child may experience a life-threatening lowering of blood pressure or death.

What is in this leaflet

1. What ABDOVIR is and what it is used for

ABDOVIR is a medicine that contains three active ingredients used to treat HIV-1 (human immunodeficiency virus type 1) 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).

ABDOVIR is used is used to treat HIV-1 infection in children from 3 months or older, weighing between 6 kg and 25 kg.

2. What you need to know before you take ABDOVIR

Do not take ABDOVIR:

- if your child is hypersensitive (allergic) to abacavir, dolutegravir, lamivudine or any of the other ingredients of ABDOVIR (see section 6). **If your child has had an allergic reaction to abacavir he/she must never receive abacavir again.**
- if your child's doctor performs blood tests and identifies a gene called HLA-B*5701
- if your child is taking a medicine called dofetilide or pilsicainide (to treat heart conditions), or fampridine (used to treat multiple sclerosis)
- if your child has moderate or severe liver problems
- if your child has moderate or severe kidney problems
- If your child is younger than 3 months
- if your child weighs less than 6 kg or more than 25 kg
- in pregnancy or breastfeeding.

Warnings and precautions

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

Hypersensitivity reactions (serious allergic reaction)

Hypersensitivity reactions to the active ingredient abacavir have developed in patients.

Who gets these reactions?

Your child is more likely to develop such a reaction if you have a gene called HLA-B*5701 (but you can get a reaction even if you do not have this gene). If possible, you will have been tested for this gene before ABDOVIR was prescribed for you. If you know you have this gene, tell your doctor before you take ABDOVIR.

What are the symptoms?

The most common symptoms are*:*

• fever (high temperature) and skin rash.

Other frequently observed symptoms include*:*

• nausea (feeling sick), vomiting (being sick), diarrhoea, abdominal (stomach) pain

• severe tiredness

• shortness of breath, cough

• headache, tingling or numbness of the hands or feet.

Other less common symptoms can include:

• mouth ulcers, sore throat, serious breathing problems, low blood pressure, swelling of the neck, inflammation of the eye (conjunctivitis), pains in the joints and muscles.

When do these reactions happen?

Hypersensitivity reactions can start at any time during treatment with ABDOVIR but are more likely during the first 6 weeks of treatment. **If you continue to take ABDOVIR, the symptoms will get worse and may be life-threatening.**

Contact your child's doctor immediately:

1. if your child gets a skin rash, OR

2. if your child gets symptoms from at least 2 of the following groups:

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

Your child's doctor may advise you to stop taking ABDOVIR.

Always carry your Alert Card while you are taking ABDOVIR.

If you have stopped taking ABDOVIR because of a hypersensitivity reaction, you must NEVER AGAIN take ABDOVIR, or any other medicine containing abacavir. If you do, within hours, your blood pressure could fall dangerously low, which could result in death.

Hypersensitivity reactions

Hypersensitivity reactions have been reported with the use of both abacavir and dolutegravir, as contained in ABDOVIR, when taken individually or when used together.

Hypersensitivity to dolutegravir

Contact your doctor promptly if your child develops a rash. Some people taking dolutegravir, one of the active substances in ABDOVIR, have had allergic reactions. Symptoms of an allergic reaction may include severe rash or rash accompanied by fever, general feeling of discomfort, illness, or unease, fatigue, muscle or joint aches, blisters, mouth ulcers/sores, conjunctivitis (pink eye), facial swelling, hepatitis, abnormal blood test results, swelling that is similar to hives. It is important that you stop taking this medicine immediately and contact your child's doctor (see Possible Side Effects).

Take special care with ABDOVIR:

- as redistribution, accumulation or loss of body fat may occur in patients receiving combination antiretroviral therapy. Contact your child's doctor if you notice changes in body fat. e.g. a hump forming on your back, loss of fat from your face, collection of fat around your abdomen
- as within the first few weeks of treatment with anti-HIV medicines, some people, particularly those that have been HIV positive for some time, may develop inflammatory reactions (e.g. pain, redness, swelling, high temperature) which may resemble an infection and may be severe. These reactions are thought to be caused by a recovery of the body's ability to fight infections, previously supressed by HIV. If you become concerned about any new symptoms, or any changes in your health after starting HIV treatment, please discuss with your child's doctor
- if your child experiences joint aches and pain, joint stiffness or difficulty moving or bone fractures tell your child's doctor as he/she may need to take calcium and vitamin D supplements to prevent further damage to your bones that may be caused by this medicine, when taken together with corticosteroids or alcohol, or if your child has a very weak immune system and are overweight
- as some patients with advanced HIV infection (AIDS) and a history of AIDS associated (opportunistic) infection, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started, some of these conditions may include pneumonia, herpes virus infections

- as HIV infection is spread by sexual contact, or by transfer of infected blood (for example, by sharing injection needles). You can still pass on HIV when taking this medicine, but the risk is lowered by effective antiretroviral therapy. Discuss with your health care provider the precautions needed to avoid infecting other people
- if your child has human immunodeficiency virus-1 (HIV-1) and hepatitis B virus (HBV), the HBV can change (mutate) during your child's treatment with ABDOVIR and become harder to treat (resistant). Your child's doctor may give him/her other medicines to treat HBV infection, if he/she has HIV-1 and HBV infections whilst taking ABDOVIR
- as HIV-infected patients with liver disease, including chronic hepatitis B or C, who are treated with antiretrovirals (medicine used to treat HIV/AIDS), have a higher risk of severe and potentially fatal liver complications. If your child is infected with HIV and hepatitis B virus, your child's doctor will carefully consider the best treatment for him/her. If your child has a history of liver disease or chronic hepatitis B infection your child's doctor may continually conduct blood tests to monitor his/her liver function
- if your child has liver disease, he/she should not be taking ABDOVIR (see Do not take ABDOVIR)
- if your child experiences nausea, vomiting, abdominal pain, generalised weakness, anorexia, and sudden unexplained weight loss, and difficulty breathing you should tell your child's doctor immediately as he/she may be experiencing lactic acidosis

- abacavir, as in ABDOVIR, has been associated with heart diseases (any complication associated with the heart not functioning as normal). Seek medical advice if your child has pre-existing heart problems as the condition could be worsened by ABDOVIR. New heart problems are also possible (such as chest pain). which should be discussed with your child's doctor
- abacavir, as in ABDOVIR, might be associated with an increased risk of heart attack If your child has heart problems, smokes or suffers from diseases that increase the risk of heart disease, such as high blood pressure and diabetes, your child's doctor should be informed
- may lead to damage of the mitochondria in babies exposed to the medicine before or after birth. Symptoms include lactic acidosis (see above), blood cell disorders (anaemia, neutropenia), numbness and tingling in the feet or hands (peripheral neuropathy), muscle overactivity (hypertonia), convulsion, or abnormal behaviour. Report to your doctor if your baby was exposed to the medicine.
- as inflammation of the pancreas (pancreatitis), with symptoms including abdominal pain, nausea and vomiting, has been observed in some patients receiving ABDOVIR
- if your child has had kidney disease or if tests have shown problems with your kidneys, notify your child’s doctor. If so, the dose of lamivudine may need to be reduced. In such cases, your child’s doctor may prescribe another medicine

- if your child is taking any other medicines at the same time as ABDOVIR it is important that you tell your child's doctor what they are as some medicines can affect the way ABDOVIR works (see Other medicines and ABDOVIR).

Other medicines and ABDOVIR

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

Do not take ABDOVIR with the following medicines:

- medicines that also contain abacavir, dolutegravir or lamivudine, as contained in ABDOVIR
- metformin (used to treat diabetes)
- medicines called antacids, to treat indigestion and heartburn and some laxatives. Do not take an antacid during the 6 hours before you take ABDOVIR, or for at least 2 hours after you take it
- calcium supplements and/or iron supplements. Do not take a calcium supplement and/or iron supplement during the 6 hours before you take ABDOVIR or for at least 2 hours after you take it
- etravirine, lopinavir/ritonavir, efavirenz, fosamprenavir/ritonavir, nevirapine, tipranavir/ritonavir, zalcitabine, emtricitabine (to treat HIV infection)
- an antibiotic containing trimethoprim and sulfamethoxazole
- cladribine, used to treat a type of leukaemia
- St. John's wort (*Hypericum perforatum*), a herbal remedy to treat depression

- dofetilide (to treat heart conditions) or pilsicainide (to treat heart irregular heartbeat)
- fampridine (also known as dalfampridine) used in multiple sclerosis.
- flucytosine (used to treat infections), may cause blood disorders and may require your health care provider to change the dose of lamivudine
- medicines such as sulfadiazine and cisplatin which may harm the kidneys and require your health care provider to check how well your kidneys are working
- rifampicin or isoniazid, to treat tuberculosis (TB) and other bacterial infections
- phenytoin and phenobarbital, to treat epilepsy
- carbamazepine, to treat epilepsy and bipolar disorder
- 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
- oral vitamin A related medicines, e g, isotretinoin (for acne therapy)
- ribavirin, to treat inflammation of the liver (hepatitis)
- alcohol may increase the effects of ABDOVIR
- dalfampridine (to improve walking in people who have multiple sclerosis).

ABDOVIR with food and drink

ABDOVIR may be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using ABDOVIR.

Do not take ABDOVIR if you are pregnant or breastfeeding your baby (see section Do not take ABDOVIR).

Women and adolescents of childbearing potential should not use ABDOVIR, unless they are on highly effective contraception.

Driving and using machines

ABDOVIR can make you dizzy and have other side effects that make you less alert.

It is not always possible to predict to what extent ABDOVIR may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ABDOVIR affects them.

ABDOVIR contains mannitol and sucralose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

ABDOVIR contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take ABDOVIR

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

Always take/use ABDOVIR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Do not change your dose, switch medicines or stop taking ABDOVIR without talking with your healthcare provider first.

The usual dose is

Patients weighing 6 kg to <10 kg: 3 tablets once daily.

Patients weighing 10 kg to <14 kg: 4 tablets once daily.

Patients weighing 14 kg to <20 kg: 5 tablets once daily.

Patients weighing 20 kg to <25 kg: 6 tablets once daily.

ABDOVIR is not suitable for patients who weigh 3 kg to less than 6 kg. Medicines containing lower amounts of the active substances are more suitable for them.

Your child can take ABDOVIR with food or between meals.

To give ABDOVIR to your child:

1. The number of tablets to be administered to the patient will be determined by his or her body weight (as shown in Table 1 above).

2. Remove the number of tablets recommended for one dose from the bottle with dry hands.

3. The tablet(s) should be placed in a container and four teaspoonfuls (20 mL) of drinking water should be added per tablet.

4. The tablets should be swirled or stirred until completely dispersed. The suspension has a strawberry flavour.

5. The child should consume the entire quantity immediately.

6. The container should be rinsed with an additional small amount of drinking water and the child should drink the contents to ensure that the whole dose is taken.

7. The tablets should not be mixed with any liquid other than water.

If you are taking any other medicines, your doctor will adjust the times between taking ABDOVIR and the other medicine.

Your doctor will tell you how long your treatment with ABDOVIR will last.

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

If you take more ABDOVIR 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 ABDOVIR

If you forget to take ABDOVIR, take a dose as soon as you remember, then continue to take ABDOVIR at the usual times. Do not take a double dose to make up for forgotten individual doses.

If you stop taking ABDOVIR

If you have HIV and hepatitis B virus (HBV) and stop taking ABDOVIR, your hepatitis infection may become worse than it was before starting treatment.

4. Possible side effects

ABDOVIR can have side effects.

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

If any of the following happens, stop using ABDOVIR and tell 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

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

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

- symptoms of infection and inflammation such as muscle weakness and/or muscle pain joint pain or swelling, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations or tremor, hyperactivity (excessive restlessness and movement)
- lactic acidosis with signs such as deep, rapid, difficult breathing, drowsiness, numbness or weakness in the limbs, feeling sick (nausea), vomiting and stomach pain
- 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 (toxic epidermal necrolysis)
- body shape changes such as fat may be lost from the legs, arms or face, extra fat may build up around the stomach, or on the breasts or internal organs, fatty lumps (sometimes called buffalo hump) may appear on the back of the neck
- inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis)
- bleeding into the skin, bruising and slow blood clotting after an injury (thrombocytopenia)

- hepatitis (swelling and inflammation of the liver, characterised by symptoms such as, abdominal pain or distension, dark urine and pale or clay-coloured stools, fatigue, fever, general itching, yellowing of the skin or eyes, loss of appetite, nausea and vomiting), jaundice, liver failure
- thoughts of killing or harming yourself, or attempting to commit suicide
- rhabdomyolysis (a condition affecting the muscles with symptoms such as dark urine and difficulty moving arms or legs).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- insomnia, abnormal dreams, depression (feeling sad), feeling anxious
- headache, dizziness
- nausea, vomiting, diarrhoea, mouth ulcer, flatulence (gas), upper stomach pain
- fatigue, general feeling of being unwell, fever, lack of energy and enthusiasm
- anorexia.

Less frequent side effects:

- stomach pain, stomach discomfort
- anaemia, changes in the white blood cell counts (neutropenia), possibly resulting in an increased risk of infection
- changes in blood tests for liver enzymes.

The following side effects have been reported but the frequency for them to occur is not known:

- muscle and joint pain
- a failure of the bone marrow to produce new red blood cells (pure red cell aplasia)
- weight increased
- peripheral neuropathy (damage to nerves outside the spinal cord, affecting the normal functioning of the body's organs and movement and/or feeling of sensation in the extremities, including your arms and legs), tingling sensation in the hands, feet or lips (pins and needles)
- rise in serum amylase (an enzyme that helps digest carbohydrates)
- skin rash, severe itching of the skin, loss of hair.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ABDOVIR.

You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store ABDOVIR

Store all medicines out of reach of children.

Keep in original container.

Store at or below 30 °C.

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

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 ABDOVIR contains

The active substances are abacavir, dolutegravir and lamivudine.

Each tablet for oral suspension contains abacavir sulphate equivalent to abacavir 60 mg, dolutegravir sodium equivalent to dolutegravir

5 mg and lamivudine 30 mg.

The other ingredients are

Acesulfame potassium

Colloidal silicon dioxide

Crospovidone

Ferric oxide

Mannitol

Microcrystalline cellulose (avicel ph101)

Opadry II pink (polyvinyl alcohol-part. Hydrolysed, titanium dioxide, macrogol/peg, talc, iron oxide red, ferrosoferric oxide)

Povidone

Silicified microcrystalline cellulose

Sodium starch glycolate

Strawberry flavour (maize maltodextrin, flavouring substances, E 1505 triethyl citrate, E 1520 propylene glycol, flavouring preparations)

Sodium stearyl fumarate

Sucralose.

What ABDOVIR looks like and contents of the pack

ABDOVIR is pink to light pink coloured oval shaped, film-coated tablets debossed with 'E06' on one side and 'LU' on the other side.

White, opaque, round HDPE bottle with one silica gel desiccant and a non-child resistant closure, packed with a printed dosing cup, this leaflet and an Alert Card in a printed carton.

Pack sizes: 30's, 60's, 90's, 120's and 180's.

Not all pack sizes are marketed.

Holder of Certificate of Registration

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