

PATIENT INFORMATION LEAFLET FOR
ABLADO PAED

SCHEDULING STATUS

S4

ABLADO PAED 60 mg / 5 mg / 30 mg Dispersible tablets

Abacavir (as sulfate), dolutegravir (as sodium) and lamivudine

Contains sweetener: aspartame 9,5 mg/tablet

Contains sugar: mannitol 14,5 mg/tablet

Read all of this leaflet carefully before your child starts taking ABLADO PAED

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your child's doctor, pharmacist nurse or other health care provider.
- ABLADO PAED has been prescribed for your child personally and you should not share their medicine with other people. It may harm them, even if their symptoms are the same as your child's.

HYPERSENSITIVITY REACTION

Patients taking ABLADO PAED may develop a hypersensitivity reaction (serious allergic reaction) to abacavir, which **can be life-threatening** if treatment with ABLADO PAED 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 ABLADO PAED 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 ABLADO PAED, 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 taking ABLADO PAED due to a hypersensitivity reaction, **HE/SHE MUST NEVER TAKE ABLADO PAED** 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 ABLADO PAED is and what it is used for
2. What you need to know before your child takes ABLADO PAED
3. How to give ABLADO PAED
4. Possible side effects
5. How to store ABLADO PAED
6. Contents of the pack and other information

1. What ABLADO PAED is and what it is used for

ABLADO PAED is a medicine that contains three active ingredients used to treat HIV-1 (human immunodeficiency virus type 1) infection: abacavir, dolutegravir and lamivudine. Abacavir and

lamivudine belong to a group of anti-retroviral medicines (medicines used to treat HIV infection) called nucleoside analogue reverse transcriptase inhibitors (NRTIs), and dolutegravir belongs to a group of anti-retroviral medicines called integrase inhibitors (INSTIs).

ABLADO PAED is used to treat HIV-1 infection in children who are at least 3 months of age and weigh 6 kg to less than 25 kg.

2. What you need to know before your child takes ABLADO PAED

Do not give your child ABLADO PAED:

- if your child is hypersensitive (allergic) to abacavir, dolutegravir or lamivudine or any of the other ingredients of ABLADO PAED (see **section 6**). **If your child has had an allergic reaction to abacavir he/she must never receive abacavir again.**
- if your child has moderate or severe liver disease.
- if your child has moderate or severe kidney disease.
- if your child's bodyweight is less than 6 kg, or 25 kg and more.
- if your child has phenylketonuria.
- if your child is taking another medicine called dofetilide or pilsicainide (to treat heart conditions).
- in pregnancy or breastfeeding.
- if your child is younger than 3 months of age.

Warnings and precautions

Take special care with ABLADO PAED:

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 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 your child has this gene variant, be sure to tell your doctor or health care provider. However, even if your child does not have this gene variant it is still possible to get this 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 (stomach) 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 ABLADO PAED. However, if they occur, this usually happens within the first six weeks of treatment. The symptoms worsen with continued treatment and may be life-threatening if treatment is continued.

Contact your doctor or health care professional immediately if:

- 1. Your child gets a skin rash OR**
- 2. Your child gets one or more symptoms from at least TWO of the following groups:**
 - Fever (high body temperature).
 - 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 taking ABLADO PAED due to a hypersensitivity reaction, **HE/SHE MUST NEVER TAKE ABLADO PAED** or any other medicine containing abacavir again, as **within hours** there may be a life-threatening lowering of blood pressure or death.

If your child has stopped taking ABLADO PAED for any reason, particularly because of side effects or other illness, it is important that you contact your doctor or health care professional before restarting. Your doctor or health care professional will check whether any symptoms may be related to this hypersensitivity reaction. If your doctor or health care professional thinks there is a possibility that they were related, you will be instructed **never to give ABLADO PAED or any other medicine containing abacavir to the child again**. It is important that you follow this advice.

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.

Hypersensitivity has been reported when abacavir was restarted in patients who had **no symptoms** of hypersensitivity before stopping.

If your child is hypersensitive to abacavir you should return all the unused ABLADO PAED for disposal. Ask your doctor, health care professional or pharmacist for advice.

Fat distribution

Redistribution, accumulation or loss of body fat may occur in patients receiving combination antiretroviral therapy.

Contact your doctor or health care provider if you notice changes in your child's body shape.

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 your doctor or health care provider immediately.

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 your child notices joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement, inform your doctor or health care professional.

Other infections

The child will need to take ABLADO PAED every day. This medicine helps to control the condition, but it is not a cure for HIV infection. Your child 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 child's doctor or health care professional. Do not stop the medicine without first talking to your doctor or health care professional.

Transmission of HIV infection

One can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy.

Discuss with your child's doctor the precautions needed to avoid infecting other people.

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 the child is being treated with ABLADO PAED your doctor or health care provider will monitor for any signs of lactic acidosis.

Mitochondrial damage

ABLADO PAED 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.

Inflammation of the pancreas

Tell your doctor if your child develops stomach pain, and nausea or vomiting. Your child may need to stop taking ABLADO PAED.

Kidney disease

Before your child uses ABLADO PAED, you should have told your doctor or health care professional if the child is suffering from or has 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 ABLADO PAED should be used. ABLADO PAED is contraindicated in patients with moderate or severe kidney impairment (see **Do not give your child ABLADO PAED**).

Liver disease

ABLADO PAED is contraindicated in patients with moderate or severe liver impairment (see **Do not give your child ABLADO PAED**). Before your child uses ABLADO PAED, you should have told your doctor or health care professional if the child has or ever had a liver disease (such as hepatitis).

Patients with chronic hepatitis B or C and treated with antiretroviral medicines are at increased risk for severe and potentially fatal liver adverse events and may require blood tests to monitor liver function.

If the child has chronic hepatitis B infection, the child should not stop treatment without instructions from your doctor or health care professional, as there may be a recurrence of hepatitis. This recurrence may be more severe if there is serious liver disease.

Heart problems

Abacavir, an active ingredient of ABLADO PAED, 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 ABLADO PAED. New heart problems are also possible (such as chest pain), which should be discussed with your child's doctor.

Heart attack

Based on data in adults, it cannot be excluded that abacavir, as in ABLADO PAED, 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.

Other medicines and ABLADO PAED

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

Some medicines can affect how ABLADO PAED works or make it more likely that your child will have side effects.

Do not give your child ABLADO PAED with any of the following medicines:

- dofetilide or pilsicainide, to treat heart conditions (see **Do not give your child ABLADO PAED**).
- metformin, to treat diabetes.
- medicines called antacids, to treat indigestion and heartburn. Do not give your child an antacid during the 6 hours before the dose of ABLADO PAED, or for at least 2 hours after the dose of ABLADO PAED.
- calcium and iron supplements. Do not give your child a calcium or iron supplement during the 6 hours before the dose of ABLADO PAED, or for at least 2 hours after the dose of ABLADO PAED.
- etravirine, efavirenz, fosamprenavir/ritonavir, nevirapine, tipranavir/ritonavir, zalcitabine, lopinavir/ritonavir, emtricitabine, or lamivudine, to treat HIV infection.
- rifampicin or isoniazid, to treat tuberculosis and other bacterial infections.
- phenytoin and phenobarbitone, to treat epilepsy.
- carbamazepine, to treat epilepsy and bipolar disorder.
- St. John's wort (*Hypericum perforatum*), a herbal remedy to treat depression.
- ribavirin, to treat inflammation of the liver (hepatitis).
- alcohol.
- trimethoprim or cotrimoxazole, used to treat bacterial infections.
- cladribine, used for cancer treatment.

- methadone, as you may experience opioid withdrawal symptoms and require a dose adjustment.
- oral vitamin A related medicines, e.g. isotretinoin (for acne therapy).

Tell your doctor if your child is taking any of above medicines. Your doctor may need to monitor your child while he/she is taking ABLADO PAED.

Taking ABLADO PAED with food, drink and alcohol

No alcohol should be consumed during treatment with ABLADO PAED.

ABLADO PAED can be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking ABLADO PAED.

Pregnancy

You should not be treated with ABLADO PAED if you are pregnant or planning to become pregnant as the safety of ABLADO PAED in human pregnancy has not been established and your unborn baby may be harmed by treatment with ABLADO PAED (see **Do not give your child ABLADO PAED**).

If you have taken ABLADO PAED during your pregnancy, your doctor or health care professional may request regular visits to monitor the development of your child. Such visits may include blood tests and other diagnostic tests.

Breastfeeding

You should not breastfeed your baby when you are taking ABLADO PAED (see **Do not give your child ABLADO PAED**).

Women who are HIV-positive should not breastfeed their babies, because HIV infection can be passed on to the baby in breast milk.

Fertility

Studies in animals showed that abacavir, dolutegravir and lamivudine do not have any effect on fertility. There are no data on the effects on human male or female fertility.

Driving and using machines

ABLADO PAED may affect your ability to drive and use machines. You should not drive or use machines until you know how treatment with ABLADO PAED affects you.

ABLADO PAED contains aspartame

ABLADO PAED contains 9,5 mg aspartame in each dispersible tablet, which is equivalent to 3,393 mg/100 mg. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

If your child has phenylketonuria, he/she should not take ABLADO PAED (see **Do not give your child ABLADO PAED**).

3. How to give ABLADO PAED

Do not share medicines prescribed for your child with any other person.

Always give your child ABLADO PAED exactly as your doctor or pharmacist has told you.

You should check with your doctor or pharmacist if you are not sure.

ABLADO PAED is available as dispersible tablets for children weighing at least 6 kg, but less than 25 kg.

ABLADO PAED should not be used by children weighing less than 6 kg, or children weighing 25 kg or more (see **Do not give your child ABLADO PAED**).

Your doctor will decide the correct dose of ABLADO PAED for your child, depending on the weight and age of the child.

ABLADO PAED should be taken once a day.

Your doctor will tell you how long your child's treatment with ABLADO PAED will last. Do not stop treatment early because your child's HIV infection may get worse.

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

The dispersible tablets should be dispersed in drinking water. When dispersed, the amount of water will depend on the number of tablets prescribed. The tablet should not be chewed, cut or crushed.

ABLADO PAED should be dispersed in water before administration. Please use the following procedure to disperse ABLADO PAED:

1. The number of tablets prescribed by your doctor for one dose should be removed from the bottle with dry hands.
2. The tablet(s) should be placed in a container and four teaspoonfuls (20 mL) of drinking water should be added per tablet.

3. The tablets should be swirled or stirred until completely dispersed. The suspension has a strawberry flavour.
4. The child should consume the entire quantity immediately.
5. 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.
6. The tablets should not be mixed with any liquid other than water.

If your child takes more ABLADO PAED than he/she 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 give ABLADO PAED

It is important not to miss doses of ABLADO PAED. If you have missed a dose, give it to your child as soon as you remember. If it is almost time for the next dose, skip the missed dose and give the next dose at the usual time. Then continue treatment as before.

Do not give a double dose to make up for the forgotten individual doses. It is important to give ABLADO PAED regularly, because irregular dosing may increase the risk of hypersensitivity (allergic) reactions.

If your child stops taking ABLADO PAED

Take ABLADO PAED for as long as your doctor recommends. Don't stop unless your doctor advises you to. Because ABLADO PAED controls and does not cure your child's condition, the child will normally need to take it continuously. You should not stop treatment unless your doctor or health care professional tells you to.

If you have any further questions on the use of ABLADO PAED, ask the prescribing doctor, health care professional or pharmacist.

4. Possible side effects

ABLADO PAED can have side effects.

Not all side effects reported for ABLADO PAED are included in this leaflet. Should your child's general health worsen or if your child experiences any untoward effects while taking ABLADO PAED, please consult your doctor, pharmacist or other healthcare professional for advice.

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.

If any of the following happens, stop giving your child ABLADO PAED and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- skin rash (without any other illness).
- a high temperature (fever).
- lack of energy (fatigue).
- muscle or joint aches.

These are all very serious side effects. If your child has them, he/she may have had a serious reaction to ABLADO PAED. Your child may need urgent medical attention or hospitalisation. Your doctor may decide to carry out tests on your child's liver, kidneys or blood and may tell you that your child should stop taking ABLADO PAED.

It is very important to talk to your doctor about any changes in your child's health.

Some side effects may only be seen in your child's blood tests and may not appear immediately after your child starts taking ABLADO PAED. If your child gets any of these effects and if they are severe, your doctor may advise your child to stop taking ABLADO PAED.

As well as the effects listed below for ABLADO PAED, other conditions can develop during combination therapy for HIV (see **section 2: Warnings and precautions**).

Tell your doctor if you notice any of the following:

Frequent side effects:

- nausea, vomiting, diarrhoea, stomach pain, sores in the mouth.
- headache.
- cough, nasal symptoms (irritation, runny nose).
- fever (increased body temperature).
- muscle pain and discomfort.
- joint pain.
- hair loss.
- tiredness, fatigue, loss of appetite.
- difficulty in sleeping (insomnia).
- itching (pruritus).
- stomach discomfort.
- dizziness.
- abnormal dreams.
- depression (feeling of deep sadness and unworthiness).
- anxiety.
- wind (flatulence).
- lethargy, feeling unwell.

Less frequent side effects:

- 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 your child more prone to infection. If he/she has a low platelet count one may notice that he/she bruises more easily.
- increases in the blood levels of some liver enzymes.
- inflammation of the pancreas (pancreatitis).
- inflammation of the liver (hepatitis), liver disorders, such as jaundice (yellowing of the skin or whites of the eyes), enlarged liver or fatty liver.
- breakdown of muscle tissue.
- 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).
- numbness, tingling sensation or sensation of weakness in the limbs (peripheral neuropathy).
- suicide thoughts (mainly in patients who have had depression or mental health problems before).
- an inflammatory condition which may develop as the immune system becomes stronger (immune reconstitution inflammatory syndrome or 'IRIS') (see **Warnings and precautions** in **section 2** of this leaflet).

Frequency not known:

- 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.
- 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 around 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.
- raised lactic acid and sugar in the blood, increased fats in the blood.
- osteonecrosis (death of bone tissue).
- liver failure (signs may include yellowing of the skin and the whites of the eyes or unusually dark urine).
- joint pain.
- muscle pain.
- weight gain.

Side effects that may show up in blood tests:

- increase in bilirubin (a substance produced by the liver) in the blood.
- an increase in the level of enzymes produced in the muscles (creatine phosphokinase, creatinine).

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, pharmacist or nurse. You can also report side effects to SAHPRA via the “**Adverse drug reaction and quality problem reporting form**”, found online under SAHPRA's publications: <https://www.sahpra.org.za/document/adverse-drug-reactions->

[and-quality-problemreporting-form/](#) or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafety@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of ABLADO PAED.

5. How to store ABLADO PAED

Store in a dry place at or below 30 °C.

Store in the original container in order to protect from moisture.

Keep the bottle tightly closed.

Do not remove the desiccant.

Store all medicines out of reach of children.

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 ABLADO PAED contains

The active substances are abacavir, dolutegravir and lamivudine. Each dispersible tablet contains abacavir sulfate 70,280 mg equivalent to abacavir 60 mg, dolutegravir sodium 5,262 mg equivalent to dolutegravir 5 mg and lamivudine 30 mg.

The other ingredients are:

Tablet core: aspartame, calcium sulphate dihydrate, colloidal silicon dioxide, crospovidone, ferric oxide red, magnesium stearate, mannitol, microcrystalline cellulose, povidone, sodium starch glycolate, strawberry cream flavour permaseal (containing waxy maize maltodextrin, propylene glycol, nature-identical flavouring substances, modified waxy maize starch, natural flavouring substances).

Film-coat: Opadry II 85F240128 Pink containing iron oxide red (E172), iron oxide yellow (E172), macrogol (E1521), polyvinyl alcohol (E1203), talc (E553b), titanium dioxide (E171).

What ABLADO PAED looks like and contents of the pack

Pink coloured, oval shaped, biconvex, film-coated tablets debossed with “C” on one side and plain on other side.

ABLADO PAED is packed in 28’s and 30’s in a 50 cc white, round, HDPE bottle with 33 mm screw cap with a liner printed “SFYP” in black, containing a 2 g silica gel bag, with or without a cardboard carton.

ABLADO PAED is packed in 84’s and 90’s in a 75 cc white, HDPE bottle with 38 mm screw cap with a liner printed “SFYP” in black, containing a 2 g silica gel bag, with or without a cardboard carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration**CIPLA MEDPRO (PTY) LTD.**

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