Patient Information Leaflet

Information for the Patient about

CIPLA-ABACAVIR 300 TABLETS AND

CIPLA-ABACAVIR ORAL SOLUTION

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet; you may need to read it again.
- If you have further questions please ask your doctor or your pharmacist.
- This medicine 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.

SCHEDULING STATUS:

S4

PROPRIETARY NAME (AND DOSAGE FORM):

CIPLA-ABACAVIR 300 (Tablets)

CIPLA-ABACAVIR ORAL SOLUTION (Oral solution)

WHAT CIPLA-ABACAVIR ORAL SOLUTION CONTAINS:

Each **CIPLA-ABACAVIR TABLET** contains the equivalent of 300 mg abacavir as abacavir sulphate. Abacavir belongs to a group of antiviral medicines, also known as antiretrovirals, called nucleoside analogue reverse transcriptase inhibitors (NRTIs).

Each millilitre **CIPLA-ABACAVIR ORAL SOLUTION** contains abacavir sulphate equivalent to 20 mg abacavir. Abacavir belongs to a group of

antiviral medicines, also known as antiretrovirals, called nucleoside analogue reverse transcriptase inhibitors (NRTIs).

CIPLA-ABACAVIR ORAL SOLUTION also contains sorbitol, which is metabolised to fructose.

Inactive ingredients for **CIPLA-ABACAVIR 300** includes microcrystalline cellulose (Avicel PH 101), sodium starch glycollate (Primojel), corn starch, hypromellose, purified water, colloidal silicon dioxide, magnesium stearate, opadry yellow (containing hypromellose 3cp and 6cp, titanium dioxide, macrogol, iron oxide yellow and polysorbate).

Inactive ingredients for **CIPLA ABACAVIR ORAL SOLUTION** includes methyl paraben, propyl paraben, non-crystallising sorbitol solution 70 %, propylene glycol, citric acid, sodium citrate, sodium citrate 20 % w/v, saccharin sodium, flavour banana 85509-H, flavour strawberry cream 11407-33, purified water and nitrogen gas.

WHAT CIPLA-ABACAVIR IS USED FOR:

CIPLA-ABACAVIR is used to treat adults and children infected with the Human Immunodeficiency Virus (HIV). **CIPLA-ABACAVIR** is always used in combination with other antiretroviral medicines for the treatment of HIV-infection.

BEFORE YOU USE CIPLA-ABACAVIR:

You or your child should not take CIPLA-ABACAVIR if you:

- Are hypersensitive or allergic to abacavir or any ingredient of the formulations.
- Suffer from moderate to severe liver function impairment.
- Are pregnant or breast feeding.
- Under 3 months of age
- Suffer from a hereditary fructose intolerance.

If you are unsure about any of these, please contact your treating doctor.

Take special care with CIPLA-ABACAVIR:

Hypersensitivity (serious allergic) reactions may occur in approximately 4 % of patients who take **CIPLA-ABACAVIR**. Some of these reactions have been fatal. These reactions are usually characterised by fever and/or a skin rash. These symptoms can occur at any time during treatment with **CIPLA-ABACAVIR** but usually appear within the first 6 weeks of starting treatment. Symptoms most often include fever, nausea, vomiting, diarrhoea, abdominal pain, rash, fatigue and generally feeling unwell. Other symptoms include muscle pain, joint pain, swelling, paraesthesia (pins and needles) and shortness of breath, sore throat or cough. These symptoms will become worse with continued therapy and may be life-threatening. These symptoms usually resolve upon discontinuation of **CIPLA-ABACAVIR.**

If you or your child should experience any of the following symptoms, you should contact your doctor IMMEDIATELY:

Skin: Rash.

Gastrointestinal tract: Nausea, vomiting, diarrhoea, abdominal pain, or mouth

ulceration.

Respiratory tract: Shortness of breath, sore throat, or cough.

Miscellaneous: Fever, fatigue, generally feeling unwell, swelling, lymph gland enlargement, hypotension (low blood pressure), conjunctivitis (inflammation of the membrane lining the eye), and anaphylaxis (severe allergic reaction).

Neurological/psychiatry: Headache, paraesthesia (pins and needles).

Musculoskeletal: Muscle pain, muscle injury, or joint pain.

Some patients with hypersensitivity reactions were initially thought to have respiratory disease (pneumonia, bronchitis, sore throat), a flu-like illness, gastroenteritis or reactions to other medications. This delay in diagnosis of hypersensitivity has resulted in **CIPLA-ABACAVIR** being continued or reintroduced, leading to more severe hypersensitivity reactions or death. Therefore, if you or your child experience any of these symptoms, it is important that you inform your treating doctor IMMEDIATELY.

If you or your child have discontinued **CIPLA-ABACAVIR** due to an allergic reaction, you or your child must NEVER take **CIPLA-ABACAVIR** or any other medicine containing abacavir again, as this may lead to the development of a life-threatening allergic reaction within hours.

An Alert Card with information about allergic reactions is included in the **CIPLA-ABACAVIR** pack. You or your child should keep this Alert Card with you at all times.

If you or your child have stopped **CIPLA-ABACAVIR** because of possible side-effects or adverse reactions, you should not restart treatment with **CIPLA-ABACAVIR** before discussing it with your treating doctor. If hypersensitivity cannot be ruled out, **CIPLA-ABACAVIR** should not be restarted.

Hypersensitivity reactions have been infrequently reported following re-introduction of **CIPLA-ABACAVIR**, where the interruption was preceded by a single key symptom (e.g. rash, fever or stomach symptoms). Very rarely hypersensitivity reactions have been reported in patients who have restarted therapy and who had no apparent preceding symptoms of a hypersensitivity reaction.

If you or your child are hypersensitive to **CIPLA-ABACAVIR**, you should return all of your unused **CIPLA-ABACAVIR** for disposal to your doctor or pharmacist.

CIPLA-ABACAVIR, as well as other NRTIs, may cause a condition known as lactic acidosis, together with an enlarged liver. Lactic acidosis, if it occurs, usually develops after a few months. Symptoms of lactic acidosis include deep, rapid breathing, drowsiness, and non-specific symptoms, such as nausea, vomiting and stomach pain. This is a rare side-effect that occurs more often in women, particularly if they are overweight. If you suffer from liver disease, you have a greater risk of developing this condition. Your treating doctor will monitor you or your child closely for this condition. Please

report any of the symptoms listed here to him/her.

Talk to your doctor if you have any of the following; liver disease, including hepatitis B or C, if you are seriously overweight (especially if you are a women) and if you have severe kidney disease, you may require extra check-ups, and blood test, while you are taking your medicine.

Tell your doctor if you have heart problems, if you smoke, or have illness that may increase your risk of heart disease such as high blood pressure, or diabetes. CIPLA-ABACAVIR may increase the risk of having a heart attack.

You or your child may still develop other infections and complications of HIV-infection while taking **CIPLA-ABACAVIR.** You/your child should remain under close supervision of your treating doctor.

Antiretroviral therapy, including **CIPLA-ABACAVIR**, has not been proven to prevent the risk of transmission of HIV to others through sexual contact or blood contamination. You should continue to use appropriate precautions to prevent this.

Taking CIPLA-ABACAVIR with food and drinks:
CIPLA-ABACAVIR can be taken without regard to meals.

Pregnancy and breast feeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

If you are pregnant or breast feeding, you should not take **CIPLA-ABACAVIR** (see **"BEFORE YOU TAKE CIPLA-ABACAVIR"**).

Driving and using machinery:

No currently available data suggests that **CIPLA-ABACAVIR** affects the ability to drive or operate machinery.

Important information about some of the ingredients in CIPLA-ABACAVIR

CIPLA-ABACAVIR ORAL SOLUTION contains sorbitol, which is metabolised to fructose and is therefore unsuitable for patients with hereditary fructose intolerance.

Taking other medicines with CIPLA-ABACAVIR

Always tell your healthcare professional if you/your child are taking any other medicines.

If you/your child are taking other medicines on a regular basis, use of this medicine with other medicines may cause undesirable interactions. Please consult your doctor or pharmacist. The potential for medicine interactions with **CIPLA-ABACAVIR** is low.

Alcohol increases the amount of abacavir, the active ingredient in **CIPLA-ABACAVIR**, in your blood. If you/your child are taking oral vitamin A-related medicines, e.g. isotretinoin, you should inform doctor, since these may also increase the amount of abacavir in your blood. As **CIPLA-ABACAVIR** increases the rate at which methadone is removed from the body, patients taking methadone will be checked for any withdrawal symptoms, and may have their methadone dose changed. Tell your doctor if you/your child are taking phenytoin for treating epilepsy, your doctor may need to monitor you while taking **CIPLA-ABACAVIR**. Tell your doctor if you are taking ribavirin for treating Hepatitis C.

HOW TO TAKE CIPLA-ABACAVIR:

CIPLA-ABACAVIR is intended for treatment of HIV-infection in adults and children. Therapy should be initiated by a physician experienced in the management of HIV infection. Always take CIPLA ABACAVIR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Adults and adolescents over 12 years:

The recommended dose of CIPLA-ABACAVIR is 300 mg (one tablet) twice daily or 600 mg (two tablets) once a day.

The recommended dose of **CIPLA-ABACAVIR ORAL SOLUTION** is 600 mg (30 ml) a day. This can be taken either as 300 mg (15 ml) twice daily or 600mg (30 ml) once a day.

Children from three months to 12 years:

The recommended dosage is 8 mg/kg twice daily up to a maximum of 600 mg twice daily. Please follow the instructions on the bottle as printed by the pharmacist or talk to your treating doctor if unsure.

Children less than three months:

There is no data available on the use of **CIPLA-ABACAVIR** in this age group.

Renal impairment:

No dosage adjustment of **CIPLA-ABACAVIR** is necessary in patients with renal dysfunction.

Hepatic impairment:

Abacavir is metabolised primarily by the liver. There is insufficient data to recommend the use of abacavir in patients with impairment of hepatic function. You or your child should not take **CIPLA-ABACAVIR** if you/your child suffer from moderate or severe liver impairment.

If you take more CIPLA-ABACAVIR than you should:

In the event of an overdosage, or if someone else has taken your medicine by mistake, you should contact your treating doctor or pharmacist or your nearest hospital emergency department for further advice.

If you forget to take CIPLA-ABACAVIR:

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

If you stop taking CIPLA-ABACAVIR:

If you/your child have stopped taking **CIPLA-ABACAVIR** for any reason, particularly because you think you/your child are having side-effects or for other illness, it is important that you contact your doctor before restarting. In some cases your doctor may ask you/your child to restart **CIPLA-ABACAVIR** in a place where you will be able to get ready access to medical care if needed.

POSSIBLE SIDE-EFFECTS:

As with any medicine, **CIPLA-ABACAVIR** may have unintended or undesirable effects. Not all side effects reported for this medicine are included in this leaflet. Should your/your child's general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Hypersensitivity (serious allergic) reactions have been reported with the use of **CIPLA-ABACAVIR.** Please see **"Take special with CIPLA-ABACAVIR"**. Almost all patients who develop hypersensitivity reactions have

fever or rash as part of the reaction. However, reactions have occurred without rash or fever.

The adverse events reported during therapy for HIV disease with **CIPLA-ABACAVIR** are similar in adults and children. For many of these events, it is unclear whether they are related to **CIPLA-ABACAVIR**, to the wide range of drugs used in the management of HIV disease or as a result of the disease process. The following adverse events occurring in patients treated with **CIPLA-ABACAVIR** are likely to be drug-related: loss of appetite, elevated blood glucose levels, elevated blood triglyceride concentrations, headache, sleeplessness, nausea, vomiting and diarrhoea. Pancreatitis (inflammation of the pancreas) has been reported, but a causal relationship to **CIPLA-ABACAVIR** treatment is uncertain. Other side-effects include liver damage with lactic acidosis (see **"Take special care with CIPLA-ABACAVIR"**), skin rash (without systemic symptoms such as fever), serious blistering skin rashes, such as Stevens-Johnson syndrome and toxic epidermal necrolysis, fatigue, and fever.

In general, adverse events have been transient and not treatment-limiting.

STORAGE AND DISPOSING OF CIPLA-ABACAVIR:

Store this medicine out of reach of children.

Store **CIPLA-ABACAVIR 300 TABLETS** at or below 25 °C.

Store **CIPLA-ABACAVIR ORAL SOLUTION** at or below 30 °C.

Discard **CIPLA-ABACAVIR ORAL SOLUTION** two months after first opening.

Do not use after the expiry date stated on the packaging material. Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

PRESENTATION OF CIPLA-ABACAVIR:

CIPLA-ABACAVIR 300 TABLETS are available in white plastic bottles containing 60 tablets.

CIPLA ABACAVIR ORAL SOLUTION is supplied in a carton containing a white coloured high density polyethylene bottle with a child-resistant cap, containing 100 ml or 240 ml or oral solution. A 5 ml calibrated syringe is included in the outer carton.

IDENTIFICATION OF CIPLA-ABACAVIR:

CIPLA-ABACAVIR 300 TABLETS: Yellow coloured, capsule-shaped, film-coated, biconvex tablet, plain on both sides.

CIPLA-ABACAVIR ORAL SOLUTION: Clear to opalescent, yellowish, strawberry and banana flavoured liquid.

REGISTRATION NUMBER:

CIPLA ABACAVIR 300: 41/20.2.8/0692

CIPLA ABACAVIR ORAL SOLUTION: 41/20.2.8/0857

NAME AND BUSINESS ADDRESS OF THE HOLDER CERTIFICATE OF REGISTRATION:

CIPLA LIFE SCIENCES (PTY) LTD

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DATE OF PUBLICATION OF THIS PATIENT LEAFLET:

November 2009

Revised: 21 July 2016