

Patient information leaflet: Information for the patient

Abacavir/Dolutegravir/Lamivudine 60 mg/5 mg /30 mg tablets for oral suspension

abacavir/dolutegravir/lamivudine

Read all of this leaflet carefully before your child start taking this medicine because it contains important information for him/her.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your child's doctor or pharmacist.
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child.
- If your child gets any side effects, talk to his/her doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension is and what it is used for
2. What you need to know before your child takes Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension
3. How to take Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension
4. Possible side effects
5. How to store Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension
6. Contents of the pack and other information

1. What Abacavir/Dolutegravir/Lamivudine Tablet for Oral Suspension is and what it is used for

Abacavir/Dolutegravir/Lamivudine Tablet for Oral Suspension 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).

Abacavir/Dolutegravir/Lamivudine Tablet for Oral Suspension is used to treat HIV-1 infection in children who weigh 10 kg to 25 kg.

Before your child is prescribed Abacavir/Dolutegravir/Lamivudine Tablet for Oral Suspension his/her doctor will arrange a test to find out whether your child carries a particular type of gene called HLA-B*5701. This medicine should not be used in patients who are known to carry the HLA-B*5701 gene. Patients with this gene are at a high risk of developing a serious hypersensitivity (allergic) reaction if they use this medicine (see 'hypersensitivity reactions' in section 4).

Abacavir/Dolutegravir/Lamivudine Tablet for Oral Suspension does not cure HIV infection; it reduces the amount of virus in your child's body, and keeps it at a low level. It also increases the number of CD4 cells in the blood. CD4 cells are a type of white blood cells that are important in helping your child's body to fight infection.

Not everyone responds to treatment with this medicine in the same way. Your child's doctor will monitor the effectiveness of the treatment.

It is not known if Abacavir/Dolutegravir/Lamivudine Tablet for Oral Suspension is safe and effective in children who weigh less than 10 kg.

2. What you need to know before your child takes Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension

Do not give your child Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension if your child

- are allergic (hypersensitive) to abacavir (or any other medicine containing abacavir), dolutegravir, lamivudine, or any of the other ingredients of this medicine (listed in section 6).
Carefully read all the information about hypersensitivity reactions in Section 4.
- takes dofetilide. Taking Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension and dofetilide can cause side effects that may be serious or life-threatening.
- has certain liver problems.

Warnings and precautions

IMPORTANT — Hypersensitivity reactions

Abacavir/Dolutegravir/Lamivudine Tablet for Oral Suspension contains abacavir and dolutegravir. Both of these active ingredients can cause a serious allergic reaction known as a hypersensitivity reaction. Your child should never take abacavir or abacavir containing products again if your child has a hypersensitivity reaction: it can be life threatening.

You must carefully read all the information under ‘Hypersensitivity reactions’ in Section 4.

The Abacavir/Dolutegravir/Lamivudine Tablet for Oral Suspension pack includes an alert card to remind you and medical staff about hypersensitivity. Detach this card and keep it with you at all times.

Some people taking Abacavir/Dolutegravir/Lamivudine Tablet for Oral Suspension or other combination treatments for HIV are more at risk of serious side effects than others. You need to be aware of the extra risks if your child:

- has or has had liver problems, including hepatitis B or C virus infection.
- has kidney problems.
- has heart problems or have diseases that increase your risk of heart disease such as high blood pressure, high cholesterol, or diabetes.
- has phenylketonuria (PKU).

Talk to his/her doctor if any of these apply to you before using this medicine.

Abacavir hypersensitivity reactions Even patients who don't have the HLA-B*5701 gene may still develop a hypersensitivity reaction (a serious allergic reaction).

Carefully read all the information about hypersensitivity reactions in Section 4 of this leaflet.

Children

This medicine is not for use in children weighing less than 10 kg.

Other medicines and Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension

Tell your child's doctor or pharmacist if your child is given, have recently given, or might be given any other medicines to your child.

Tell your child's doctor about all the medicines your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medicines interact with Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension. Keep a list of the medicines to show your child's doctor and pharmacist when your child gets a new medicine.

- You can ask your child's doctor or pharmacist for a list of medicines that interact with Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension.
- **Do not start giving a new medicine to your child without telling your child's doctor.** Your child's doctor can tell you if it is safe to give Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension with other medicines.

Pregnancy and breast feeding

- are pregnant or plan to become pregnant. One of the medicines in Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension called dolutegravir may harm unborn baby.
 - Your doctor may prescribe a different medicine than Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension if you are planning to become pregnant or if pregnancy is confirmed during the first 12 weeks of pregnancy.
 - If you can become pregnant, your doctor may perform a pregnancy test before you start treatment with Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension.
 - If you can become pregnant, you and your doctor should talk about the use of effective birth control (contraception) during treatment with Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension.
 - Tell your doctor right away if you are planning to become pregnant, you become pregnant, or think you may be pregnant during treatment with Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension.
- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension.**
 - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
 - Abacavir, dolutegravir and lamivudine passes to your baby in your breastmilk.

Driving and using machines

Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension can make you dizzy and have other side effects that make you less alert.

Do not drive or operate machinery unless you are sure your alertness has not been affected.

Abacavir/Dolutegravir/Lamivudine Tablet for Oral Suspension contains aspartame and sodium

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

This medicine also contains aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if your child has phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension

Always use this medicine exactly as your child's doctor has told you. Check with your child's doctor if you are not sure.

Read the Instructions for Use at the end of this leaflet for detailed instructions on how to prepare a dose of Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension.

- **Your child should take Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension exactly as your child's doctor tells you to give it.**
- Do not change the dose, switch medicines or stop giving Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension to your child without talking with your child's doctor first.
- **Abacavir, Dolutegravir and Lamivudine Tablets are not the same as Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension and cannot be substituted for each other. Check to make sure your child receives the correct dosage**

form each time your child's prescription is filled to avoid using the wrong medicine.

- Your child's doctor will prescribe Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension based on your child's weight.
- Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension should be dispersed in drinking water.
- Do **not** chew, cut, or crush Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension.
- Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension may be taken with or without food.
- If your child takes antacids, laxatives, or other medicines that contain aluminum, magnesium, or buffered medicines, Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension should be taken at least 2 hours before or 6 hours after your child take these medicines.
- If your child needs to take iron or calcium supplements by mouth during treatment with Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension:
 - If your child takes Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension with food, your child may take these supplements at the same time that you give Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension.
 - If your child does not take Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension with food, give your child Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension at least 2 hours before or 6 hours after you give these supplements.

For very young children who cannot swallow tablets, Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension should be dispersed in water before administration. Please use the following procedure to disperse Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension:

1. The number of tablets to be administered to your child will be determined by his or her body weight (as shown in table above).
2. Remove the number of tablets recommended for one dose from the bottle with dry hands.
3. Place the tablet(s) in a container and add four teaspoonfuls (20 mL) of drinking water per tablet.
4. Swirl or stir until the tablets disperse completely. The suspension has a strawberry flavour.
5. Your child should consume the entire quantity immediately.
6. Rinse the container with an additional small amount of drinking water and let your child drink the contents to assure that the whole dose is taken.
7. Do not mix the tablets with any liquid other than water.

After full dispersion, administer the oral suspension within 30 minutes of mixing.

If your child takes more Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension than he/she should

If your child takes too much Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension, call his/her doctor or go to the nearest hospital emergency room right away.

If you forget to give Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension

If your child misses a dose of Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension, give it as soon as you remember. Do not take 2 doses at the same time or take more than the doctor tells your child to take.

If your child stops taking Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension

Do not run out of Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension. The virus in your child's blood may increase and the virus may become harder to treat. When the supply starts to run low, get more from your child's doctor or pharmacy.

If you have any further questions on the use of this medicine, ask your child's doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension can cause serious side effects, including:

- **Serious allergic reactions (hypersensitivity reaction)** that can cause death have happened with Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension and other abacavir-containing products. The risk of this allergic reaction to abacavir is much higher if your child has a gene variation called HLA-B*5701. Your child’s doctor can determine with a blood test if your child have this gene variation.

If your child gets a symptom from 2 or more of the following groups while taking Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension, call the doctor right away to find out if your child should stop taking Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension.

	Symptom(s)
Group 1	Fever
Group 2	Rash
Group 3	Nausea, vomiting, diarrhea, abdominal (stomach area) pain
Group 4	Generally ill feeling, extreme tiredness, or achiness
Group 5	Shortness of breath, cough, sore throat

A list of these symptoms is on the alert card your child’s pharmacist gives your child. **Carry this alert card with you at all times.**

If your child stops Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension because of an allergic reaction, never give your child Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension (abacavir, dolutegravir and lamivudine), or any other medicine that contains abacavir or dolutegravir again.

- If your child has an allergic reaction, dispose of any unused Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension. Ask the pharmacist how to properly dispose of medicines.
- If your child takes Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension or any other abacavir-containing medicine again after your child has had an allergic reaction, **within hours** your child may get **life-threatening symptoms** that may include **very low blood pressure** or **death**.
- If your child stops Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension for any other reason, even for a few days, and your child is not allergic to Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension, talk with the doctor before taking it again. Taking Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension again can cause a serious allergic or life-threatening reaction, even if your child never had an allergic reaction to it before.

If the doctor tells you that your child can take Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension again, start giving it when your child are around medical help or people who can call a doctor if you need one.

- **Worsening of Hepatitis B virus (HBV) infection.** Your child’s doctor will test your child for HBV infection before he/she start treatment with Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension. If your child has HBV infection and take Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension, your child’s HBV may get worse (flare-up) if you stop giving Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension. A “flare-up” is when your child’s HBV infection suddenly returns in a worse way than before.

- Do not run out of Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension. Refill the prescription or talk to your child’s doctor before Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension is all gone.
 - Do not stop Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension without first talking to your child’s doctor.
 - If your child stops taking Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension, the doctor will need to check your child’s health often and do blood tests regularly for several months to check the liver function and monitor your child’s HBV infection. It may be necessary to give your child a medicine to treat hepatitis B. Tell the doctor about any new or unusual symptoms your child may have after your child stops taking Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension.
- **Resistant HBV.** If you have human immunodeficiency virus-1 (HIV-1) and HBV, the HBV can change (mutate) during your treatment with Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension and become harder to treat (resistant). Your doctor may give you other medicines to treat HBV infection if you have HIV-1 and HBV infections and take Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension.

Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension can cause serious side effects, including:

- **See “What is the most important information I should know about Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension?”**
- **Liver problems.** People with a history of hepatitis B or C virus may have an increased risk of developing new or worsening changes in certain liver function tests during treatment with Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension. Liver problems including liver failure have also happened with abacavir, dolutegravir and lamivudine in people without a history of liver disease or other risk factors. Liver failure resulting in liver transplant has also been reported with abacavir, dolutegravir and lamivudine. Your child’s doctor may do blood tests to check your liver. **Call your child’s doctor right away if your child develops any of the signs or symptoms of liver problems listed below.**
 - your child’s skin or the white part of your child’s eyes turns yellow (jaundice)
 - dark or “tea-colored” urine
 - light colored stools (bowel movements)
 - loss of appetite
 - nausea or vomiting
 - pain, aching, or tenderness on the right side of your child’s stomach area
- **Too much lactic acid in your child’s blood (lactic acidosis).** Too much lactic acid is a serious medical emergency that can lead to death. **Call your child’s doctor right away if your child get any of the following symptoms that could be signs of lactic acidosis:**
 - feel very weak or tired
 - unusual (not normal) muscle pain
 - trouble breathing
 - stomach pain with nausea and vomiting
 - feel cold, especially in your child’s arms and legs
 - feel dizzy or lightheaded
 - have a fast or irregular heartbeat
- **Lactic acidosis can also lead to severe liver problems,** which can lead to death. Your child’s liver may become large (hepatomegaly) and your child may develop fat in your liver (steatosis). **Call your child’s doctor right away if your child gets any of the signs or symptoms of liver problems which are listed above under “Liver problems”.**
- **Your child may be more likely to get lactic acidosis or severe liver problems if your child is female or very overweight (obese).**
- **Changes in your child’s immune system (Immune Reconstitution Syndrome)** can happen when your child starts taking HIV-1 medicines. Your child’s immune system may get stronger and begin to fight infections that have been hidden in your child’s body for a long time. Tell the doctor right away if your child starts having new symptoms after your child starts taking Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension.
- **Heart attack.** Some HIV-1 medicines including Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension may increase your child’s risk of heart attack.

- **The most common side effects of abacavir, dolutegravir and lamivudine include:**

- trouble sleeping
- headache
- tiredness

These are not all the possible side effects of Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension.

Reporting of side effects

If your child gets any side effects, talk to the doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the local reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the bottle and carton after 'EXP'. The expiry date refers to the last day of that month.

Store below 30°C (86°F). Keep bottle tightly closed. Protect from moisture. Do not remove desiccant.

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Abacavir/Dolutegravir/Lamivudine Tablet for Oral Suspension contains

- The active substance is abacavir, dolutegravir and lamivudine. Each tablet for oral suspension contains 60 mg of abacavir (as sulfate), 5 mg of dolutegravir (as sodium) and 30 mg of lamivudine.
- The other ingredients are:
 - Tablet core: aspartame, calcium sulphate dihydrate, colloidal silicon dioxide, crospovidone, iron oxide red, magnesium stearate, mannitol, microcrystalline cellulose, povidone, purified water, sodium starch glycolate, strawberry cream flavour permaseal
 - Film-coat: iron oxide yellow, iron oxide red, macrogol, polyvinyl alcohol-part hydrolyzed, talc, titanium dioxide

What Abacavir/Dolutegravir/Lamivudine Tablets for Oral Suspension looks like and contents of the pack

Abacavir/Dolutegravir/Lamivudine Tablet for Oral Suspension is presented as pink coloured, oval shaped biconvex film coated tablet debossed with "C" on one side and plain on other side.

Each carton having Bottle of 30 tablets with desiccant and non-child-resistant closure. with one 40-mL dosing cup

Each carton having Bottle of 90 tablets with desiccant and non-child-resistant closure. with one 40-mL dosing cup

Supplier

Cipla Ltd.
Cipla House,
Peninsula Business Park,
Ganapatrao Kadam Marg,

Lower Parel, Mumbai 400 013.
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Manufacturer

Cipla Limited,
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