

## PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

### Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg<sup>1</sup>

Abacavir (as sulfate)/Lamivudine

**Read all of this leaflet carefully before your child starts taking this medicine because it contains important information for your child.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- 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 those of your child.
- If your child gets any side effects, talk to your health care provider. This includes any possible side effects not listed in this leaflet. See section 4.

#### **HYPERSENSITIVITY REACTION**

Patients taking Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg may develop a hypersensitivity reaction (serious allergic reaction) to abacavir, which **can be life-threatening** if treatment with Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg 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 Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg 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 HEALTH CARE PROVIDER IMMEDIATELY for advice on whether your child should stop taking Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg 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 discontinued Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg due to a hypersensitivity reaction, **HE/SHE MUST NEVER TAKE** Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg or any other medicine containing abacavir (e.g. abacavir tablets, abacavir/dolutegravir/lamivudine tablets or abacavir/lamivudine/zidovudine tablets) again, as **within hours** your child may experience a life-threatening lowering of blood pressure or death.

<sup>1</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority’s (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

## What is in this leaflet

1. What Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg is and what it is used for
2. What you need to know before your child takes Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg
3. How to take Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg
4. Possible side effects
5. How to store Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg
6. Contents of the pack and other information

### 1. WHAT ABACAVIR(AS SULFATE)/LAMIVUDINE DISPERSIBLE TABLETS 120MG/60MG IS AND WHAT IT IS USED FOR

Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg is a combination medicine containing abacavir and lamivudine. Both of these drugs belong to a group of antiviral medicines, also known as antiretrovirals, called *nucleoside analogue reverse transcriptase inhibitors (NRTIs)*. These are used to treat Human Immunodeficiency Virus (HIV) infection.

Abacavir and Lamivudine are used in combination with other antiretroviral medicines for the treatment of HIV infection. They reduce the amount of HIV in your child's body, and keep it at a low level. They also increase CD4 cell counts in the blood. CD4 cells are a type of white blood cell that are important in maintaining a healthy immune system to help fight infection. Response to treatment with abacavir and Lamivudine varies between patients. Your child's health care provider will be monitoring the effectiveness of the treatment.

Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg may improve your child's condition, but it is not a cure for the HIV infection. HIV infection is a disease spread by contact with blood or sexual contact with an infected individual. Treatment with Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg has not been shown to eliminate the risk of passing HIV infection on to others by sexual contact or by blood transfer. Therefore, you/your child must continue to take appropriate precautions to avoid giving the virus to others.

*This medicine is intended for use in children. Safety information on use in adults is also provided.*

### 2. WHAT YOU NEED TO KNOW BEFORE YOUR CHILD TAKES ABACAVIR(AS SULFATE)/LAMIVUDINE DISPERSIBLE TABLETS 120MG/60MG

#### **Your child should not be given Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg if:**

- he/she is allergic to abacavir (or any other medicine containing abacavir- (e.g. abacavir/lamivudine/zidovudine tablets, abacavir/dolutegravir/lamivudine or abacavir tablets), lamivudine or any of the other ingredients of this medicine (listed in section 6)
- he/she has severe liver disease.

#### **Warnings and precautions**

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

### **Hypersensitivity reactions**

Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg contains **abacavir** (which is also an active substance in medicines such as **abacavir/lamivudine/zidovudine tablets**, **abacavir/dolutegravir/lamivudine tablets** and **abacavir tablets**). Abacavir can cause a serious allergic reaction known as a hypersensitivity reaction. These hypersensitivity reactions have been seen more frequently in people taking medicines that contain abacavir.

#### **Who gets these reactions?**

Anyone taking Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg could develop a hypersensitivity reaction to abacavir, which could be life threatening if they continue to take Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg.

Your child is more likely to develop this reaction if he/she has a gene called HLA-B\*5701 (but you can get a reaction even if you do not have this gene). Your child should have been tested for this gene before Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg was prescribed for him/her. If you know your child has this gene, tell your child's healthcare provider before your child takes Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg.

About 3 to 4 in every 100 patients treated with abacavir in a clinical trial who did not have the HLA-B\*5701 gene developed a hypersensitivity reaction.

#### **What are the symptoms?**

The most common symptoms are:  
Fever (high temperature) and skin rash

Other common symptoms are:  
Nausea (feeling sick), vomiting (being sick), diarrhoea, abdominal (stomach) pain, severe tiredness.

Other symptoms include:  
Pains in the joints or muscles, swelling of the neck, shortness of breath, sore throat, cough, occasional headaches, inflammation of the eye (conjunctivitis), mouth ulcers, low blood pressure, tingling or numbness of the hands or feet.

#### **When do these reactions happen?**

Hypersensitivity reactions can start at any time during treatment with Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg. but more likely during the first 6 weeks of treatment.

#### **Contact your healthcare provider 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 abdominal pain
  - severe tiredness or achiness, or generally feeling ill.

**Your healthcare provider may advise your child to stop taking Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg.**

**If your child has stopped taking Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg**

If your child has stopped taking Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg because of a hypersensitivity reaction, your child must NEVER AGAIN take Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg, or any other medicine containing abacavir (e.g. abacavir/lamivudine/zidovudine tablets, abacavir/dolutegravir/lamivudine tablets or abacavir tablets). If your child does, within hours, your child's blood pressure could fall dangerously low, which could result in death.

If your child has stopped taking Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg for any reason- especially because you think your child is having side effects, or because your child has other illness:

Talk to your child's healthcare provider before your child's symptoms start again. Your healthcare provider will check whether your child's symptoms were related to a hypersensitivity reaction. If the healthcare provider thinks they may have been, you will be told never again to give Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg or any other medicine containing abacavir (e.g. abacavir/lamivudine/zidovudine tablets, abacavir/dolutegravir/lamivudine tablets or abacavir tablets). It is important that you follow this advice.

Occasionally hypersensitivity reactions have developed in people who start taking abacavir containing medicines again, but who had only one symptom on the Alert Card before they stopped taking it.

Very rarely patients who have taken medicines containing abacavir in the past without symptoms of hypersensitivity have developed a hypersensitivity reaction when they start taking these medicines again.

If your healthcare provider advises that your child can start taking Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg again, you may be asked to give your child's first doses in a place where your child will have ready access to medical care if needed.

If your child is allergic to Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg, return all the unused Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg for safe disposal. Ask your healthcare provider for advice.

The Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg pack includes an Alert Card, to remind you and medical staff about hypersensitivity reactions. Detach this card and keep it with your child at all times.

*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 the health care provider. However, even if your child does not have this gene variant it is still possible to get this reaction. About 3 to 4 in every 100 patients treated with abacavir in a clinical trial who did not have a gene called HLA-B\*5701 developed a hypersensitivity reaction (a serious allergic 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 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 Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg. 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 CHILD'S HEALTH CARE PROVIDER IMMEDIATELY for advice on whether he/she should stop Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg 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
  - 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 discontinued Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg due to a hypersensitivity reaction, **HE/SHE MUST NEVER TAKE** Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg 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 Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg for any reason, particularly because of side effects or other illness, it is important that you contact the health care provider before restarting. The health care provider will check whether any symptoms may be related to this hypersensitivity reaction. If the health care provider thinks there is a possibility that they were related, you will be instructed **never to give Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg or any other medicine containing abacavir to the child again.** It is important that you follow this advice.

Occasionally 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.

On very rare occasions hypersensitivity has been reported when abacavir was restarted in patients who had **no symptoms** of hypersensitivity before stopping.

If your child is allergic to abacavir you should return all the unused Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg for disposal. Ask the health care provider for advice.

#### *Kidney disease*

Before your child uses Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg, you should have told the health care provider 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 Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg should be used.

#### *Liver disease*

Before your child uses Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg, you should have told the health care provider if the child has or ever had a liver disease (such as hepatitis).

Patients with chronic hepatitis B or C and treated with antiretroviral agents 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 the health care provider, as there may be a recurrence of hepatitis. This recurrence may be more severe if there is serious liver disease.

#### *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 (see section 3). While the child is being treated with Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg the health care provider will monitor for any signs of lactic acidosis.

#### *Fat distribution*

Redistribution, accumulation or loss of body fat may occur in patients receiving combination antiretroviral therapy. Contact the 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 the 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 the health care provider.

#### *Heart attack*

Based on data in adults, it cannot be excluded that abacavir might be associated with an increased risk of heart attack. If one has heart problems, smokes or suffers from diseases that increase the risk of heart disease such as high blood pressure and diabetes, the doctor should be informed.

#### *General*

The child will need to take Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg 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 health care provider. Do not stop the medicine without first talking to the health care provider.

#### **Other medicines and Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg**

Tell your child's health care provider if the child is taking, has recently taken or might take any other medicines, including medicines obtained without a prescription.

The amount of abacavir in your child's blood may be altered by the concomitant use with:

- alcohol
- oral vitamin A related medicines, e.g. isotretinoin (for acne therapy)
- rifampicin (medicine for treatment of tuberculosis)
- phenobarbital and phenytoin (medicines for treatment of seizures)
- lopinavir with ritonavir, tipranavir with ritonavir (other antiretroviral medicines)

As 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.

Lamivudine should not be used in combination with

- emtricitabine (other antiretroviral medicine)
- other medicine containing lamivudine, used to treat HIV infection or hepatitis B infection
- high dose co-trimoxazole (antibiotic)
- cladribine, used to treat hairy cell leukaemia

#### **Some medicines can make it more likely that your child will have side effects, or make side effects worse. These include:**

- co-trimoxazole, to treat bacterial infections

Tell your doctor if your child is taking this.

Some medicines interact with Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg

These include:

- phenytoin, for treating epilepsy.

Tell your healthcare provider if your child is taking phenytoin. Your healthcare provider may need to monitor him/her while he/she is taking Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg.

- methadone, used as a heroin substitute. Abacavir increases the rate at which methadone is removed from the body. If one is taking methadone, he/she will be checked for any withdrawal symptoms. His/her methadone dose may need to be changed.  
Tell your healthcare provider if your child is taking methadone.

### **Taking Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg with food and drink**

Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg can be taken with or without food.

### **Pregnancy and breast-feeding**

If you become pregnant, or are planning to become pregnant, you must contact your healthcare provider to discuss the potential benefits and risks of your antiretroviral therapy to you and your child.

If you have taken abacavir/Lamivudine during your pregnancy, your healthcare provider may request regular visits to monitor the development of your child. Such visits may include blood tests and other diagnostic tests.

In children whose mothers took nucleoside and nucleotide analogues during pregnancy, the benefit of the reduced risk of being infected with HIV is greater than the risk of suffering from side effects.

If you are interested in breastfeeding your baby, you should discuss the risks and benefits with your doctor or healthcare provider.

### **Driving and using machines**

No studies on the effects of abacavir on the ability to drive and use machines have been performed. However, one should take into account the state of one's health and the possible side effects of abacavir and Lamivudine before considering driving or using machines.

### **Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg contains aspartame**

Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg contains aspartame, which is a source of phenylalanine. This may be harmful for people with phenylketonuria.

## **3. HOW TO TAKE ABACAVIR (AS SULFATE)/LAMIVUDINE DISPERSIBLE TABLETS 120MG/60MG**

Always give this medicine exactly as your child's healthcare provider has told you. Check with the healthcare provider if you are not sure.

### Children 6 weeks of age and above

Number of tablets by weight band to be taken twice daily (approximately 12 hours apart) or once daily.



Body weight	Recommended number of tablets	
	Twice daily dosing (morning and evening)	Once daily dosing
3- 5.9 kg	½ tablet	1 tablet
6- 9.9 kg	½ tablet in the morning and 1 tablet in the evening	1 and ½ tablets
10-13.9 kg	1 tablet	2 tablets
14-19.9 kg	1 tablet in the morning and 1 ½ tablet in the evening	2 and ½ tablets
20-24.9 kg	1½ tablets	3 tablets

**For very young children who cannot swallow tablets, Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg should be dispersed in water before administration. Please use the following procedure to disperse Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg:**

1. The number of tablets to be administered to each patient 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 two teaspoonfuls (10 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.

Children weighing 25 kg or more, adolescents and adults

For these patient groups other formulations with higher amounts of the active substances are available.

Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg can be taken with or without food.

**If one takes more Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg than one should**

If your child accidentally takes too much medicine you should tell your child's healthcare provider, or contact your nearest hospital emergency department for further advice.

**If you forget to give Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg**

It is important not to miss doses of Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg. If you forget to give a dose of your child's medicine, and notice this within 6 hours, give the missed dose as soon as possible. Give the next regular dose as scheduled. If you notice this later, give the normal dose to the child when the next one is due. Do not give a double dose to make up for the forgotten individual doses. It is important to give Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg regularly, because irregular dosing may increase the risk of hypersensitivity reactions.

### **If one stops taking Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg**

Because this medicine controls and does not cure your child's condition, the child will normally need to take it continuously. You should not stop treatment unless the healthcare provider tells you to.

If you have any further questions on the use of this medicine, ask the healthcare provider.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them. When treating HIV infection, it is not always possible to tell whether some of the undesirable effects that occur are caused by Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg, by other medicines being taken at the same time, or by the HIV disease. For this reason, it is very important that you inform the healthcare provider about any changes in your child's health.

**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.

The following list of side effects is mainly based on data from adult patients.

### **Common side effects** (may affect up to 1 in 10 people):

- hypersensitivity reaction
- skin rash (without any other illness)
- nausea, vomiting, diarrhoea, stomach pain
- headache
- cough, nasal symptoms (irritation, runny nose)
- fever
- muscle pain and discomfort
- joint pain
- hair loss
- tiredness, fatigue, loss of appetite
- difficulty in sleeping (insomnia)

### **Uncommon side effects** (may affect up to 1 in 100 people and may show up in blood tests):

- 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.

### **Rare side effects** (may affect up to 1 in 1,000 people):

- inflammation of the pancreas (pancreatitis)
- inflammation of the liver (hepatitis), liver disorders, such as jaundice, enlarged liver or fatty liver

- breakdown of muscle tissue

**Very rare side effects** (may affect up to 1 in 10,000 people):

- 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)

**Not known** (frequency cannot be estimated from the available data):

The following side effects have been reported in patients treated with medicines of the group of NRTIs, to which also abacavir and Lamivudine belong. However, frequency estimates for these effects are not available:

- 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)
- immune reactivation syndrome (see “Warnings and precautions” in section 2 of this leaflet).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell the health care provider.

### **Reporting of side effects**

If you get any side effects, talk to your health care provider. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE ABACAVIR (AS SULFATE)/LAMIVUDINE DISPERSIBLE TABLETS 120MG/60MG**

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

Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the label after {EXP}. The expiry date refers to the last day of that month.

Do not throw away any medicines via waste water or household waste. Ask your healthcare provider 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 (as sulfate)/lamivudine dispersible tablets 120mg/60mg contains

The active ingredients are 120 mg abacavir (as sulfate) and 60 mg lamivudine.

The other ingredients are microcrystalline cellulose, sodium starch glycolate, hypromellose, corn starch, strawberry cream flavour, aspartame, colloidal silicon dioxide and magnesium stearate.

### What Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg looks like and contents of the pack

White to off white capsule shaped, biconvex, uncoated tablet debossed with “CJ” on one side and deep scoreline on other side.

The tablet can be divided into equal doses.

Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg are packed in 85cc HDPE container with 38 mm CRC polypropylene cap, having a silica gel bag of 1g and rayon sani coil. Pack size: 60 tablets

Abacavir (as sulfate)/lamivudine dispersible tablets 120mg/60mg are packed in 50cc HDPE container with 38 mm CRC polypropylene cap, having a silica gel bag of 1g and rayon sani coil. Pack size: 30 tablets

#### Supplier

Cipla Limited  
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Ganpatrao Kadam Marg, Lower Parel  
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India  
Phone: 9122 24826000  
Fax: 9122 24826120

#### Manufacturer

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India

**For any information about this medicinal product, please contact the supplier.**

**This leaflet was first approved in June 2017**

Section 6 updated in June 2019

Detailed information on this medicine is available on the World Health Organization (WHO) web site: <https://extranet.who.int/prequal>