PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

DUMIVA DISPERSIBLE TABLETS (120 mg/60 mg, dispersible tablets)

Abacavir/Lamivudine

Contains sweetener: Aspartame 15 mg

Read all of this leaflet carefully before your child starts taking DUMIVA DISPERSIBLE TABLETS

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

HYPERSENSITIVITY REACTION

Patients taking DUMIVA DISPERSIBLE TABLETS which contain abacavir and lamivudine may develop a hypersensitivity reaction (serious allergic reaction) which can be life-threatening and can cause death, if treatment with DUMIVA DISPERSIBLE TABLETS is continued. It is essential that you read the information on this reaction in this leaflet under the heading "**Take special care with DUMIVA DISPERSIBLE TABLETS**". There is also an alert card included in the DUMIVA DISPERSIBLE TABLETS pack to remind you and medical staff about DUMIVA DISPERSIBLE TABLETS's hypersensitivity. This card should be removed from the pack and kept with you/the patient at all times. The text on this card is shown below.

CONTACT YOUR DOCTOR IMMEDIATELY for advice on whether you or the patient should stop taking DUMIVA DISPERSIBLE TABLETS 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 discontinued DUMIVA DISPERSIBLE TABLETS due to a hypersensitivity reaction, **HE/SHE MUST NEVER TAKE** it again, or any other medicine containing abacavir, as **within hours** your child may experience a life-threatening lowering of their blood pressure or death.

What is in this leaflet

1. What DUMIVA DISPERSIBLE TABLETS are and what they are used for
2. What you need to know before you give DUMIVA DISPERSIBLE TABLETS
3. How to give DUMIVA DISPERSIBLE TABLETS
4. Possible side effects
5. How to store DUMIVA DISPERSIBLE TABLETS
6. Contents of the pack and other information

1 What DUMIVA DISPERSIBLE TABLETS are and what they are used for

What DUMIVA DISPERSIBLE TABLETS are

DUMIVA DISPERSIBLE TABLETS belong to a group of antiviral medicines, also known as antiretrovirals, called nucleoside analogue reverse transcriptase inhibitors (NRTIs).

What they are used for

These are used to treat Human Immunodeficiency Virus (HIV) infection. DUMIVA DISPERSIBLE TABLETS are used in combination with other antiretroviral medicines for the treatment of HIV infection. DUMIVA DISPERSIBLE TABLETS are always used with other anti-HIV-1 medicines.

DUMIVA DISPERSIBLE TABLETS 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 DUMIVA DISPERSIBLE TABLETS 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 product is intended for use in children. Safety information on its use in adults is also provided.

2 What you need to know before you give DUMIVA DISPERSIBLE TABLETS

Do not take DUMIVA DISPERSIBLE TABLETS

- If your child previously suffered an allergic reaction to any of the active ingredients, abacavir or lamivudine, or any other ingredient of DUMIVA DISPERSIBLE TABLETS (listed in section 6).
- If your child has liver disease.
- If your child has kidney disease.
- If your child is taking emtricitabine (a medicine to treat HIV infection).
- If he/she has phenylketonuria.
- If she is pregnant or breastfeeding her baby (see Pregnancy, breastfeeding and fertility).

Warnings and precautions

Before giving DUMIVA DISPERSIBLE TABLETS, tell your child's doctor about all of your child's medical conditions, including if:

- Your child has been tested and know whether or not he/she has a particular gene variation called HLA-B*5701.
- Your child has heart problems, smoke or suffer from diseases that increase his/her risk of heart disease e.g. high blood pressure, high cholesterol or diabetes.

If you are not sure about any of these, please consult your child's doctor.

Take special care with DUMIVA DISPERSIBLE TABLETS

Hypersensitivity reaction (serious allergic reaction)

The most important symptoms of this reaction are high temperature (fever) and a skin rash. Other frequently seen signs or symptoms are nausea, vomiting, diarrhoea, abdominal pain, shortness of breath, cough, headache, and severe tiredness. Other symptoms may be joint or muscle pain, swelling of the neck and sore throat. Occasionally swelling of the eye, ulcers in the mouth or low blood pressure may occur. The symptoms of this allergic reaction can occur at any time during treatment with DUMIVA DISPERSIBLE TABLETS. However, they usually occur in the first six weeks of treatment and get worse with continued treatment. If you are caring for a child who is being treated with DUMIVA DISPERSIBLE TABLETS it is important you understand the information about this hypersensitivity reaction. If your child gets the symptoms described below, it is essential you follow the instructions given.

The hypersensitivity reaction can be life-threatening or fatal if treatment with DUMIVA DISPERSIBLE TABLETS is continued.

You should contact your doctor immediately for advice on whether you should stop taking/giving DUMIVA DISPERSIBLE TABLETS if:

- **You/the patient get(s) a skin rash OR**
- **You/the patient get(s) one or more symptom 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 general ill feeling.

If your child discontinued DUMIVA DISPERSIBLE TABLETS because of a hypersensitivity reaction **HE/SHE MUST NEVER TAKE DUMIVA DISPERSIBLE TABLETS** or any other medicine containing abacavir again as within hours he/she may experience a life-threatening lowering of his/her blood pressure or death. Occasionally life-threatening hypersensitivity reactions have occurred when DUMIVA DISPERSIBLE TABLETS were restarted in patients who got only one of the symptoms on the alert card before stopping.

If your child is hypersensitive to DUMIVA DISPERSIBLE TABLETS, you should return all unused tablets to the doctor or pharmacist for proper disposal.

DUMIVA DISPERSIBLE TABLETS can cause a condition called lactic acidosis, together with an enlarged liver. This rare but serious side effect occurs more often in women. If you/the patient have(s) liver disease you/they may also be more at risk of getting this condition while you/they are being treated with DUMIVA DISPERSIBLE TABLETS. The doctor will monitor you/the patient for any signs that you/they may be developing lactic acidosis.

- If your child has ever had liver disease, including hepatitis B or C (if he/she has hepatitis B infection, do not stop giving DUMIVA DISPERSIBLE TABLETS without a doctor's advice, as the hepatitis may come back).
- If your child is very overweight (especially if your child is a girl).
- Your child's body shape may change. If your child is taking combination antiretroviral therapy for HIV he/she may find that his/her body shape changes, because of changes in fat distribution.

- You must contact your doctor if your child experiences joint aches and pain, joint stiffness or difficulty in movement.
- DUMIVA DISPERSIBLE TABLETS help to control your child's condition but is not a cure for HIV infection. Your child will need to take it every day. Do not stop giving DUMIVA DISPERSIBLE TABLETS without first talking to your child's doctor. If you are concerned that your child may be developing symptoms of a hypersensitivity reaction (see above), call the doctor immediately who will advise you whether you need to stop giving DUMIVA DISPERSIBLE TABLETS.
- Your child may continue to develop other infections and other illnesses associated with HIV disease. You should therefore keep in regular contact with your child's doctor while giving DUMIVA DISPERSIBLE TABLETS.

Treatment with DUMIVA DISPERSIBLE TABLETS has not been shown to decrease the risk of passing HIV infection on to others by sexual contact or by blood transfer. Your child should continue to use appropriate precautions to prevent this.

To protect other people from becoming infected with HIV:

- Your child must use a condom when he has oral or penetrative sex.
- Your child must not risk blood transfer – for example, do not share needles.

Risk of cardiovascular events

- It cannot be excluded that abacavir may increase the risk of having cardiovascular events.
- Tell your doctor if you have cardiovascular problems, if you smoke, or have other illnesses that may increase your risk of cardiovascular diseases such as high blood pressure, or diabetes. Do not stop taking DUMIVA DISPERSIBLE TABLETS unless your doctor advises you to do so.

Children and adolescents

Do not give DUMIVA DISPERSIBLE TABLETS to children younger than 3 months and weighing more than 25 kg.

Other medicines and DUMIVA DISPERSIBLE TABLETS

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

Do not take DUMIVA DISPERSIBLE TABLETS if you are already taking any of the following medicines:

- Emtricitabine (other antiretroviral medicine). See Do not take DUMIVA DISPERSIBLE TABLETS.

It is important to tell your child's doctor about all the medicines that he/she is taking or has taken, including those you have bought. Especially tell your child's doctor if your child is taking any of the following medicines:

- Rifampicin (used to treat TB).
- Phenobarbital (used to treat epilepsy).
- Phenytoin (used to treat epilepsy).
- Methadone (medicine used to prevent withdrawal symptoms in people who are addicted to opioid substances such as heroin).
- Trimethoprim + sulfamethoxazole (co-trimoxazole) (two antibiotics which can also be given together to treat some types of infections).
- Ganciclovir (antiviral medicine used to treat infections caused by a virus called cytomegalovirus).
- Foscarnet (belongs to a group of medicines called anti-viral medicines).
- Zalcitabine (used in combination with other medicines for HIV infection).
- Other medicines containing lamivudine, used to treat HIV infection or hepatitis B infection.
- Cladribine, used to treat hairy cell leukaemia.
- Alcohol.
- Oral vitamin A related medicines, e.g. isotretinoin (for acne therapy).
- Ribavirin, for treating hepatitis C. Abacavir may make the combination of ribavirin and pegylated interferon less effective at reducing levels of hepatitis C virus in the body.

DUMIVA DISPERSIBLE TABLETS with food and drink

DUMIVA DISPERSIBLE TABLETS can be taken with or without food.

Pregnancy, breastfeeding and fertility

You should not be treated with DUMIVA DISPERSIBLE TABLETS if you are pregnant or planning to become pregnant as the safe use of DUMIVA DISPERSIBLE TABLETS in human pregnancy has not been established. The doctor will advise whether your child should continue to take DUMIVA DISPERSIBLE TABLETS.

Breastfeeding

After receiving DUMIVA DISPERSIBLE TABLETS it is likely to be found in human breast milk. Your child is therefore advised not to breastfeed while receiving DUMIVA DISPERSIBLE TABLETS.

If your child is pregnant or breastfeeding, think your child may be pregnant or are planning to have a baby, please consult your child's doctor, pharmacist or other health care provider for advice before your child starts taking this medicine.

Driving and using machines

DUMIVA DISPERSIBLE TABLETS are intended for children from 3 months to 12 years. DUMIVA DISPERSIBLE TABLETS is unlikely to affect a patient's ability to operate machinery or drive.

Patients must not operate machines or drive unless they are feeling well. If there are any concerns, tell the doctor.

Important information about some of the ingredients of DUMIVA DISPERSIBLE TABLETS

DUMIVA DISPERSIBLE TABLETS contain aspartame which is a source of phenylalanine. This may be harmful for people with phenylketonuria.

3 How to give DUMIVA DISPERSIBLE TABLETS

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

Always give DUMIVA DISPERSIBLE TABLETS exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

Treatment should be prescribed and started by a medical doctor experienced in the management of HIV infection.

Children between 3 months and 12 years of age

- The recommended dose of DUMIVA DISPERSIBLE TABLETS for children is based on the child's body weight and will be determined by the doctor.
- The doctor will also explain how and when the tablets must be taken.

Your doctor will tell you how long your child's treatment with DUMIVA DISPERSIBLE TABLETS will last. Do not stop treatment early.

If you have the impression that the effect of DUMIVA DISPERSIBLE TABLETS is too strong or too weak, talk to the doctor or pharmacist.

If you give more DUMIVA DISPERSIBLE TABLETS than you should

If you accidentally give the child too many DUMIVA DISPERSIBLE TABLETS contact the nearest hospital emergency department for further advice.

In the event of overdosage, speak to a doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre for help.

If you forget to give your child DUMIVA DISPERSIBLE TABLETS

If you forget to give a dose of DUMIVA DISPERSIBLE TABLETS, give it as soon as you remember and then continue as before.

Do not give a double dose to make up for missed individual doses.

Effects when treatment with DUMIVA DISPERSIBLE TABLETS is stopped

If you have stopped giving DUMIVA DISPERSIBLE TABLETS for any reason, especially if you think your child is having side effects, or for any other illness, it is important that you contact your child's doctor before restarting.

In some cases the doctor will ask you to restart DUMIVA DISPERSIBLE TABLETS under direct medical supervision or where medical care can be easily accessed by yourself or others. If the doctor thinks that there is a possibility that your child's symptoms were related to a hypersensitivity reaction, you may be told never to give DUMIVA DISPERSIBLE TABLETS or any other medicine containing abacavir again.

4 Possible side effects

DUMIVA DISPERSIBLE TABLETS can have side effects.

Not all side effects reported for DUMIVA DISPERSIBLE TABLETS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DUMIVA DISPERSIBLE TABLETS, please consult your health care provider for advice.

If any of the following happens, stop giving DUMIVA DISPERSIBLE TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.
- 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).

Some patients treated with DUMIVA DISPERSIBLE TABLETS and do not have a gene called HLA-B*5701 developed a serious allergic reaction.

The hypersensitivity reaction can be life-threatening or fatal if treatment with DUMIVA DISPERSIBLE TABLETS is continued. **You should contact your child's doctor immediately for advice on whether you should stop giving him/her DUMIVA DISPERSIBLE TABLETS if:**

- **Your child gets a skin rash OR**
- **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 (stomach) pain.
  - Severe tiredness or aches and pains or generally feeling ill.

These are all very serious side effects. If you or your child have them, you may have had a serious reaction to DUMIVA DISPERSIBLE TABLETS. You may need urgent medical attention or hospitalisation.

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

- Swelling of the eye.
- mouth ulcers.
- low blood pressure.
- Headache.
- Lactic acidosis (is more likely to develop in people who have liver disease or in very overweight people, especially girls). It can be life-threatening, causing failure of internal organs, liver disorders, such as jaundice, enlarged liver or fatty liver, hepatitis, inflammation of the pancreas (pancreatitis).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Loss of appetite (anorexia).
- Skin rash.
- Difficulty in sleeping.

- Cough.
- Irritated or runny nose.
- Hair loss.
- Joint pains.
- Muscle pain and discomfort.

Less frequent side effects:

- A low red blood cell count (anaemia) or low white blood cell count (neutropenia).
- Redistribution/accumulation of body fat [fat may be lost from the legs, arms or face; extra fat may build up around the tummy or on the breasts; fatty lumps (sometimes called “buffalo hump”) may appear on the back of the neck].
- Sensation of weakness in the limbs.
- Increase in an enzyme called amylase.
- Breakdown of muscle tissue.

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 “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of DUMIVA DISPERSIBLE TABLETS.

5 How to store DUMIVA DISPERSIBLE TABLETS

Store all medicines out of reach of children.

- Store at or below 30 °C.
- Protect from light.
- Store the tablets in the original container.
- Keep the container tightly closed.
- Do not use after the expiry date stated on the label.
- Do not store in the bathroom.
- 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 DUMIVA DISPERSIBLE TABLETS contains

The active substances are lamivudine and abacavir in one dispersible tablet.

The other ingredients are croscarmellose sodium, magnesium stearate, microcrystalline cellulose, strawberry flavour (artificial flavours, benzyl alcohol, maltodextrin, propylene glycol, triethyl citrate).

What DUMIVA DISPERSIBLE TABLETS looks like and contents of the pack

What DUMIVA DISPERSIBLE TABLETS looks like:

White to off-white, round, biconvex tablet with a criss-cross score on both sides of the tablet and debossed with “M” on the top left of the score over “A” on the bottom left of the score and “L” on the bottom right of the score on one side of the tablet.

DUMIVA DISPERSIBLE TABLETS are presented in the following:

Contents of the pack:

High density polyethylene (HDPE) bottle pack (marketable pack) comprising of a white opaque HDPE bottle with absorbent cotton and white opaque polypropylene (PP) screw cap with a package insert in an outer carton. Pack size of 28’s, 30’s and 60’s.

Not all pack sizes are marketed.

Holder of Certificate of Registration

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This leaflet was last revised in

17 October 2024

Registration number

49/20.2.8/0462

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website.