PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

MYLAMBA Film-coated tablets

Abacavir 600 mg and lamivudine 300 mg

Sugar free

WARNING:

LACTIC ACIDOSIS AND SEVERE HEPATOMEGALY WITH STEATOSIS, INCLUDING FATAL CASES, HAVE BEEN REPORTED WITH THE USE OF NUCLEOSIDE ANALOGUES ALONE OR IN COMBINATION WITH OTHER ANTIRETROVIRALS.

Patients taking MYLAMBA film-coated 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 MYLAMBA is continued. It is essential that you read the information on this reaction in this leaflet under the heading “Take special care with MYLAMBA”. There is also an alert card included in the MYLAMBA pack to remind you and medical staff about MYLAMBA hypersensitivity. This card should be removed from the pack and kept with you at all times. The text on this card is shown below. Patients taking MYLAMBA may develop a hypersensitivity reaction (serious allergic reaction) which can be life-threatening if treatment with MYLAMBA is continued.

CONTACT YOUR DOCTOR IMMEDIATELY for advice on whether you should stop taking MYLAMBA if:

- you get a skin rash OR
- you get one or more symptoms from at least TWO of the following groups:

- shortness of breath, sore throat or cough
- nausea and vomiting or diarrhoea or abdominal pain
- severe tiredness or achiness or general ill feeling

If you have discontinued MYLAMBA due to a hypersensitivity reaction YOU MUST NEVER TAKE it again, or any other medicine containing abacavir again, as within hours you may experience a life-threatening lowering of your blood pressure or death.

Read all of this leaflet carefully before you start taking MYLAMBA

- 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.
- MYLAMBA 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.

What is in this leaflet

1. What MYLAMBA is and what it is used for
2. What you need to know before you take MYLAMBA
3. How to take MYLAMBA
4. Possible side effects
5. How to store MYLAMBA
6. Contents of the pack and other information

1. What MYLAMBA is and what it is used for

MYLAMBA belongs 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. MYLAMBA is used in combination with other antiretroviral medicines for the treatment of HIV infection in adults and adolescents from 12 years of age. MYLAMBA is always used with other anti-HIV-1 medicines.

2. What you need to know before you receive MYLAMBA

Do not take MYLAMBA:

- if you are allergic (hypersensitive) to abacavir, lamivudine or any of the other ingredients of MYLAMBA (listed in section 6).
- if you have liver disease.
- if you have kidney disease.
- if you are taking emtricitabine (a medicine to treat HIV infection).
- if you are a child below 12 years of age (weighing less than 40 kg) as the necessary dose adjustment cannot be made.

If you are not sure whether you should be taking MYLAMBA, please discuss with your doctor before taking this medicine.

Warnings and precautions

Take special care with MYLAMBA:

- if you have been tested and know whether or not you have a particular gene variation called HLA-B*5701.
- if you are pregnant, planning to become pregnant or breast-feeding.
- if you have heart problems, smoke or suffer from diseases that increase your risk of heart disease e.g. high blood pressure, high cholesterol or diabetes.

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 MYLAMBA. 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 MYLAMBA 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 MYLAMBA is continued. You should contact your doctor immediately for advice on whether you should stop taking MYLAMBA if:

- you get a skin rash OR
- you get 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 you have discontinued MYLAMBA because of a hypersensitivity reaction YOU MUST NEVER TAKE MYLAMBA or any other medicine containing abacavir again as within hours you may experience a life-threatening lowering of your blood pressure or death. Occasionally life-threatening hypersensitivity reactions have occurred when MYLAMBA was restarted in patients who got only one of the symptoms on the alert card before stopping.

If you are hypersensitive to MYLAMBA you should return all unused tablets to your doctor or pharmacist for proper disposal.

MYLAMBA 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 have liver disease you may also be more at risk of getting this condition while you are being treated with MYLAMBA. Your doctor will monitor you for any signs that you may be developing lactic acidosis.

- If you have ever had liver disease, including hepatitis B or C (if you have hepatitis B infection, do not stop taking MYLAMBA without your doctor's advice, as your hepatitis may come back).
- If you are very overweight (especially if you are a woman).
- Your body shape may change. If you are taking combination antiretroviral therapy for HIV you may find that your body shape changes, because of changes in fat distribution.
- You must contact your doctor if you experience joint aches and pain, joint stiffness or difficulty in movement.
- MYLAMBA helps to control your condition but is not a cure for HIV infection.

You will need to take it every day. Do not stop MYLAMBA without first talking to your doctor. If you are concerned that you may be developing symptoms of a hypersensitivity reaction (see above), call your doctor immediately who will advise you whether you need to stop taking MYLAMBA.

- You may continue to develop other infections and other illnesses associated with HIV disease. You should therefore keep in regular contact with your doctor while taking MYLAMBA.

- Treatment with MYLAMBA has not been shown to decrease the risk of passing HIV infection on to others by sexual contact or by blood transfer. You should continue to use appropriate precautions to prevent this.
- To protect other people from becoming infected with HIV:
  - use a condom when you have oral or penetrative sex,
  - do not risk blood transfer – for example, do not share needles.

Other medicines and MYLAMBA

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

It is important to tell your doctor about all the medicines you are taking or have taken, including those you have bought yourself.

Interactions relevant to MYLAMBA:

- 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).

MYLAMBA with food and drink

MYLAMBA can be taken with or without food.

Pregnancy, breastfeeding and fertility

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

Pregnancy:

The safe use of MYLAMBA in human pregnancy has not been established. Your doctor will advise whether you should continue to take MYLAMBA.

Breastfeeding:

After taking MYLAMBA it is likely to be found in human breast milk. You are therefore advised not to breastfeed while taking MYLAMBA.

Driving and using machines

MYLAMBA is unlikely to affect your ability to operate machinery or drive. However, do not operate machines or drive unless you are feeling well. If you have any concerns consult your doctor.

3. How to take MYLAMBA

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

Always take MYLAMBA exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure.

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

Take MYLAMBA for as long as your doctor recommends. Don’t stop unless your doctor advises you to. Take great care not to miss any doses if at all possible. Swallow the tablet whole with water.

MYLAMBA Tablets can be taken with or without food.

The usual dose in adults and adolescents from 12 years of age, who weigh at least 40 kg, is one tablet daily.

Your doctor will tell you how long your treatment with MYLAMBA will last.

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

If you take more MYLAMBA than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take MYLAMBA

It is important to take MYLAMBA as prescribed to ensure you get maximum benefit. If you forget to take a dose, take it as soon as you remember and then continue as before. Do not take a double dose to make up for forgotten individual doses.

If you stop taking MYLAMBA

If you have stopped taking MYLAMBA for any reason, especially if you think you are having side effects, or for other illness, it is important that you contact your doctor before restarting. In some cases you doctor will ask you to restart MYLAMBA under direct medical supervision or where medical care can be easily accessed by yourself or others. If your doctor thinks that there is a possibility your symptoms were related to hypersensitivity reaction, you may be told never to take MYLAMBA or any other medicine containing abacavir again.

4. Possible side effects

MYLAMBA can have side effects.

Not all side effects reported for MYLAMBA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MYLAMBA, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking MYLAMBA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Some patients treated with MYLAMBA and did 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 MYLAMBA is continued. You should contact your doctor immediately for advice on whether you should stop taking MYLAMBA if:
  - you get a skin rash OR
  - you get 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 (stomach) pain
    - severe tiredness or aches and pains or generally feeling ill.

These are all very serious side effects. If you have them, you may have had a serious reaction to MYLAMBA. 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.

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:

- anorexia,
- difficulty in sleeping,
- cough,
- irritated or runny nose,
- skin rash,
- 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),
- lactic acidosis (is more likely to develop in people who have liver disease or in very overweight people, especially women). It can be life-threatening, causing failure of internal organs,
- 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,
- liver disorders, such as jaundice, enlarged liver or fatty liver, hepatitis,
- 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),
- inflammation of the pancreas (pancreatitis),
- 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 MYLAMBA.

5. How to store MYLAMBA

Store all medicines out of reach of children.

Do not store above 30 °C. Protect from light.

Store the tablets in the original container.

Keep the blisters in the outer carton until required for use.

Keep the container tightly closed.

Do not take the medicine after the expiry date stated on the bottle/blister/carton.

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 MYLAMBA contains

- The active substances are abacavir and lamivudine. Each MYLAMBA film-coated tablet contains 600 mg of abacavir as abacavir sulphate and 300 mg lamivudine.
- The other ingredients are colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, sodium starch glycollate in the core of the tablet. The tablet is coated with Opadry Yellow.

- Sugar free.

What MYLAMBA looks like and contents of the pack

Yellow coloured, biconvex, film-coated tablet, debossed with “M157” on one side and plain on the other side.

Contents of the pack:

MYLAMBA is presented in the following:

High Density Polyethylene (HDPE) bottle pack (marketable pack) comprising of a round wide mouth white HDPE bottle with white opaque polypropylene (PP) screw cap with aluminium induction sealing wad with a package insert in an outer carton. Pack size of 28’s or 30.

High Density Polyethylene (HDPE) bottle pack (marketable pack) comprising of a blue wide mouth blue opaque HDPE bottle with blue opaque polypropylene screw cap with aluminium induction sealing liner wad with a package insert in an outer carton. Pack size of 28’s or 30.

PVC/Aclar blister pack (marketable pack) comprises of clear, transparent, PVC film-coated with Aclar on one side (i.e. PVC/Aclar) and hard tempered aluminium foil (coated with VMCH heat seal lacquer) on other side with a package insert in an outer carton. Pack size of 28’s or 30.

Not all packs may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

To follow