

SCHEDULING STATUS**S4****CABRIMIV, 600 mg/300 mg, film-coated tablets****Abacavir/Lamivudine****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 CABRIMIV 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 CABRIMIV is continued. It is essential that you read the information on this reaction in this leaflet under the heading "Take special care with CABRIMIV". There is also an alert card included in the CABRIMIV pack to remind you and medical staff about CABRIMIV 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 CABRIMIV may develop a hypersensitivity reaction (serious allergic reaction) which can be life-threatening if treatment with CABRIMIV is continued.

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

1.3.2.1 Patient Information Leaflet

- **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 CABRIMIV 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 CABRIMIV

- 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.
- CABRIMIV 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 CABRIMIV is and what it is used for.
2. What you need to know before you take CABRIMIV.
3. How to take CABRIMIV.
4. Possible side effects.
5. How to store CABRIMIV.

1.3.2.1 Patient Information Leaflet

6. Contents of the pack and other information.

1. What CABRIMIV is and what it is used for

What CABRIMIV is:

CABRIMIV 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.

What it is used for:

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

2. What you need to know before you receive CABRIMIV

Do not take CABRIMIV:

- if you are allergic (hypersensitive) to any of the active ingredients abacavir, lamivudine or any of the other ingredients of CABRIMIV (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 CABRIMIV, please discuss with your doctor before taking this medicine.

Warnings and precautions

1.3.2.1 Patient Information Leaflet

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 CABRIMIV. 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 CABRIMIV 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 CABRIMIV is continued. You should contact your doctor immediately for advice on whether you should stop taking CABRIMIV 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 CABRIMIV because of a hypersensitivity reaction YOU MUST NEVER TAKE CABRIMIV 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

1.3.2.1 Patient Information Leaflet

occurred when CABRIMIV was restarted in patients who got only one of the symptoms on the alert card before stopping.

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

CABRIMIV 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 CABRIMIV. Your doctor will monitor you for any signs that you may be developing lactic acidosis.

Take special care with CABRIMIV:

- 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 breastfeeding.
- 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.
- If you have ever had liver disease, including hepatitis B or C (if you have hepatitis B infection, do not stop taking CABRIMIV 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

1.3.2.1 Patient Information Leaflet

stiffness or difficulty in movement.

- CABRIMIV helps to control your condition but is not a cure for HIV infection.

You will need to take it every day. Do not stop CABRIMIV 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 CABRIMIV.

- 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 CABRIMIV.
- Treatment with CABRIMIV 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.

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 MYLAMBA unless your doctor advises you to do so.

1.3.2.1 Patient Information Leaflet

Children and adolescents

Do not give MYLAMBA to adolescents and children (from 12 years of age), **weighing less than 40 kg.**

Other medicines and CABRIMIV

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 CABRIMIV:

- 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).

These medicines should not be used with CABRIMIV:

- Emtricitabine, to treat HIV infection (see 'Do not take CABRIMIV).

1.3.2.1 Patient Information Leaflet

- Other medicines containing lamivudine, used to treat HIV infection or hepatitis B infection.
- Cladribine, used to treat hairy cell leukaemia.

CABRIMIV with food and drink

CABRIMIV 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 CABRIMIV.

Pregnancy:

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

Breastfeeding:

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

Driving and using machines

CABRIMIV is unlikely to affect your ability to operate machinery or drive. However, do not operate machines or drive unless you are feeling well. It is not always possible to predict to what extent MYLAMBA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MYLAMBA affects them. If you have any concerns consult your doctor.

1.3.2.1 Patient Information Leaflet

3. How to take CABRIMIV

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

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

The usual dose is:

- The usual dose in adults and adolescents from 12 years of age, who weigh at least 40 kg, is one tablet daily.
- Treatment should be prescribed and initiated by a medical practitioner experienced in the management of HIV infection.
- Take CABRIMIV 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.
- CABRIMIV Tablets can be taken with or without food.
- Your doctor will tell you how long your treatment with CABRIMIV will last.
- If you have the impression that the effect of CABRIMIV is too strong or too weak, tell your doctor or pharmacist.

If you take more CABRIMIV than you should

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

If you forget to take CABRIMIV

1.3.2.1 Patient Information Leaflet

It is important to take CABRIMIV 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 CABRIMIV

- If you have stopped taking CABRIMIV 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 CABRIMIV 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 CABRIMIV or any other medicine containing abacavir again.

4. Possible side effects

CABRIMIV can have side effects.

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

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

- Some patients treated with CABRIMIV and did not have a gene called HLA-B*5701 developed a serious allergic reaction.

1.3.2.1 Patient Information Leaflet

The hypersensitivity reaction can be life-threatening or fatal if treatment with CABRIMIV is continued. You should contact your doctor immediately for advice on whether you should stop taking CABRIMIV 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.
- 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.
- Liver disorders, such as jaundice, enlarged liver or fatty liver, hepatitis (inflammation of the liver).
- 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).

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

1.3.2.1 Patient Information Leaflet

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:

The following side effects have been reported frequently:

- anorexia,
- difficulty in sleeping,
- cough,
- irritated or runny nose,
- skin rash,
- hair loss,
- joint pains,
- muscle pain and discomfort.

The following side effects have been reported less frequently:

- 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,

1.3.2.1 Patient Information Leaflet

- 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 CABRIMIV.

5. How to store CABRIMIV

- 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 store in bathrooms.
- 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.

1.3.2.1 Patient Information Leaflet

toilets).

6. Contents of the pack and other information

What CABRIMIV contains

The active substances are abacavir and lamivudine.

Each CABRIMIV 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 CABRIMIV looks like and contents of the pack

What MYLAMBA looks like:

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

Contents of the pack:

CABRIMIV is presented in the following:

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

Pack size of 28's or 30's.

1.3.2.1 Patient Information Leaflet

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

Pack size of 28's or 30's.

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's.

Not all packs may be marketed.

Holder of Certificate of Registration

VIATRIS HEALTHCARE (PTY) LTD

4 Brewery Street

Isando

1600

This leaflet was last revised in

Date of publication: March 2023

Date of revision of text: 16 October 2024

1.3.2.1 Patient Information Leaflet

Registration number

56/20.2.8/0117

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website.