

PATIENT INFORMATION LEAFLET FOR

DAMICAVA

SCHEDULING STATUS: **S4**

DAMICAVA 600 mg/50 mg/300 mg, film-coated tablets

Abacavir, Dolutegravir and Lamivudine

Contains sugar: mannitol (145 mg/tablet).

Read all of this leaflet carefully before you start taking DAMICAVA:

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

6. Contents of the pack and other information.

1. What DAMICAVA is and what it is used for

DAMICAVA is indicated for the treatment of Human Immunodeficiency Virus (HIV) infection in adults and adolescents from 18 years of age.

2. What you need to know before you take DAMICAVA

Do not take DAMICAVA if:

- you are hypersensitive to dolutegravir, abacavir, lamivudine or to any of the other ingredients of DAMICAVA (listed in **section 6**).
- you are also taking with dofetilide or pilsicainide whilst under treatment with DAMICAVA.
- you suffer from moderate to severe liver malfunctioning.
- you suffer from moderate to severe kidney impairment.
- you are also being treated with metformin; an oral medicine used for diabetes (controls blood sugar levels).

Warnings and precautions

Take special care with DAMICAVA:

Hypersensitivity (allergic reactions) to abacavir, an active ingredient of DAMICAVA:

Abacavir hypersensitivity can be life-threatening. The hypersensitivity reaction is characterised by the appearance of symptoms indicating multi-organ involvement. Usually, fever and/or rash can occur as part of the syndrome. Some of the other symptoms of hypersensitivity may include fatigue, malaise, gastrointestinal symptoms, such as nausea, vomiting, diarrhoea, or abdominal pain, and breathing problems, sore throat, cough and abnormal chest x-ray findings (predominantly infiltrates, which can be localised). The symptoms of this hypersensitivity reaction

can occur at any time during treatment with abacavir, but usually occur within the first six weeks of therapy. The symptoms worsen with continued therapy and can be life-threatening. These symptoms usually resolve upon discontinuation of abacavir.

You need to stop treatment and consult your doctor immediately if you suspect you are hypersensitive to abacavir. If it has been confirmed that you are hypersensitive to abacavir, always ensure your doctor is aware of this hypersensitivity, and do not take DAMICAVA or any other medicine containing abacavir.

Hypersensitivity (allergies) to dolutegravir:

Hypersensitivity reactions have been reported with dolutegravir and were characterised by rash, constitutional findings and sometimes, organ dysfunction, including liver injury (characterised by abdominal pain and swelling, yellowing of the skin and eyes and dark urine). Discontinue use of DAMICAVA immediately if signs or symptoms of hypersensitivity reactions develop (including, but not limited to, severe rash or rash accompanied by fever, general malaise, fatigue, muscle or joint aches, blisters, oral lesions, conjunctivitis, facial swelling (oedema), hepatitis, eosinophilia, angioedema). These hypersensitivity reactions may be life-threatening if dolutegravir treatment is not discontinued as early as possible.

Accumulation of fat deposits in the liver coupled with increased lactic acid in your body:

A fatal condition characterised by fatty deposits in your liver and abnormally high levels of lactic acid can occur. Symptoms include nausea, vomiting, abdominal pain, breathing problems, fatigue and unexplained weight loss. These conditions may lead to liver failure. You must consult your doctor if you have experienced any of these symptoms while on treatment with DAMICAVA.

Pancreatitis (inflammation of the pancreas due to injury):

Your pancreas (an organ involved in the digestive system) may be harmed by use of DAMICAVA. Signs of pancreatitis include abdominal pain, nausea or vomiting. Discontinue use of DAMICAVA and consult your doctor if you suspect development of pancreatitis.

Kidney impairment:

If you suffer from any form of kidney impairment, you should inform your doctor.

Liver impairment:

Use of DAMICAVA can result in liver injury, leading to enlargement of the liver due to non-alcoholic fatty liver disease (hepatic steatosis). If you have pre-existing liver dysfunction, inform your doctor before continuing with DAMICAVA treatment. If your liver conditions worsens during treatment with DAMICAVA, consult your doctor immediately and discontinue treatment. Signs of liver injury include abdominal pain and swelling, yellowing of the skin and eyes and dark urine.

Mitochondrial dysfunction:

DAMICAVA can cause abnormalities in your body cells, leading to mitochondrial dysfunction, which can cause harm to the nervous system/brain of yourself or your unborn/newborn baby which may lead to fits (convulsion) and abnormal behaviour. You should not be treated with DAMICAVA if you are pregnant or breastfeeding your baby. (see **Pregnancy and breastfeeding**).

Fat redistribution:

DAMICAVA can lead to accumulation of body fat or fat redistribution, with signs including central obesity, dorso-cervical fat, enlargement (buffalo hump), peripheral wasting, facial wasting and breast enlargement. This, as well as changes to your blood fats and blood sugar can put you at risk of heart-related illnesses.

Immune reconstitution inflammatory syndrome (IRIS):

If you show any symptoms of infection while you are taking DAMICAVA. People with advanced HIV infection (AIDS) have weak immune systems and are more likely to develop serious infections (opportunistic infections). When these people start with the treatment, they may find that old hidden infections (such as tuberculosis) flare up, causing signs and symptoms of inflammation (such as localised swelling, area appears red and hot, painful). These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight these infections.

Osteonecrosis:

Osteonecrosis is a condition where bones deteriorate (may even break in severe cases) and joints also get badly affected. A combination of risk factors like long exposure to ART, (medicines used to treat HIV) advanced HIV condition, corticosteroid use, alcohol consumption, weak immune system, being overweight can lead to development of osteonecrosis. You must seek medical advice if you suffer from movement difficulties and painful or stiff joints.

Opportunistic infections:

You may be at risk of opportunistic (uncommon/rare) and other infections while taking the DAMICAVA treatment. Always consult your doctor and get treatment if you experience any infection. Infections usually are indicated by fever and flu-like symptoms.

Dual infections- HIV and Hepatitis B or C virus:

If you have both HIV and hepatitis B or C disease (or pre-existing liver problems), you are potentially at risk of severe liver impairment. Ensure your doctor knows of your condition as the he/she needs to work out the right or suitable treatment for your conditions.

The risk of HIV transmission to others:

DAMICAVA ART does not prevent the risk of transmission of HIV to others through sexual contact or blood contamination. Appropriate precautions should continue to be employed.

Heart problems:

Abacavir, an active constituent of DAMICAVA, has been associated with heart diseases or other cardiovascular events (any complication associated with the heart not functioning as normal). Seek medical advice if you have pre-existing heart problems as your condition could be exacerbated by the use of DAMICAVA. New onset of heart related problems is also possible (such as chest pain), which also warrants medical intervention.

Medicine interactions:

Do not take other ART medications that contain constituents of DAMICAVA, namely, abacavir, lamivudine and dolutegravir (see **Other medicines and DAMICAVA**).

Do not take DAMICAVA simultaneously with metformin due to the high risk of side effects associated with metformin (see **Other medicines and DAMICAVA** and **Do not take DAMICAVA if**).

If you are also using iron, magnesium, aluminium or calcium supplements, take care to take DAMICAVA 2 hours before the supplements or 6 hours after the supplements. Alternatively, take DAMICAVA with food (see **Other medicines and DAMICAVA**).

Other medicines and DAMICAVA:

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

Tell your doctor or health care provider if you are already using any of the following:

Medicines used to treat HIV-1 infections:

- Etravirine, efavirenz, nevirapine, tipranavir/ritonavir, fosamprenavir/ritonavir: can cause DAMICAVA to be ineffective.
- Atazanavir, ritonavir: may increase effectiveness of DAMICAVA.
- These medicines may not affect or be affected by DAMICAVA: nelfinavir, lopinavir/ritonavir, tenofovir, darunavir/ritonavir, lopinavir/ritonavir/etravirine and darunavir/ritonavir + etravirine.
- Emtricitabine: co-administration may decrease effectiveness of both DAMICAVA and emtricitabine.
- Zalcitabine: co-administration is not recommended as DAMICAVA can interfere with activity of zalcitabine

Other medicines:

- Do not use metformin together with DAMICAVA as life-threatening side effects may occur.
- Do not use together with heart medicines dofetilide and pilsicainide due to increased risk of life-threatening side effects associated with dofetilide and pilsicainide.
- Do not use together with medicines for seizures (oxcarbazepine, phenytoin, phenobarbital and carbamazepine) and St. John's wort as DAMICAVA effectiveness may be reduced.
- Iron supplements and magnesium, aluminium or calcium antacids: DAMICAVA 2 hours before the supplements or 6 hours after the supplements. Alternatively, take DAMICAVA with food (see **Taking special care with DAMICAVA**).
- When DAMICAVA is used with rifampicin (antibiotic used to treat TB), an additional 50 mg dose of dolutegravir must be administered.

DAMICAVA with food and drink

DAMICAVA can be taken with or without food.

Pregnancy and breastfeeding

All women who are able to have children, should be counselled about the potential risk of neural tube defects with the use of dolutegravir, a component of DAMICAVA in pregnancy, therefore a suitable method of contraception should be discussed with your doctor before starting treatment with DAMICAVA.

All women who are able to have children should perform a pregnancy test before starting treatment with DAMICAVA, this is to exclude the unintentional use of DAMICAVA during the first trimester of pregnancy.

If you plan on becoming pregnant, your doctor will need to discuss the risks and benefits of starting or continuing treatment with DAMICAVA versus another medicine regimen.

It should be noted that the use of dolutegravir, a component of DAMICAVA, was associated with a small increase in the likelihood of neural tube defects (Birth defects of the brain and spine) compared to non-dolutegravir regimens. Most neural tube defects occur within the first 4 weeks of pregnancy which is approximately 6 weeks after your last menstrual cycle (period).

If you fall pregnant and are taking dolutegravir, a component of DAMICAVA, the benefits and risks of continuing dolutegravir, a component of DAMICAVA, versus switching to another medicine regimen should be discussed with you, by your doctor.

Dolutegravir, a component of DAMICAVA, may be used in the second and third trimester of pregnancy when the expected benefit outweighs the potential risk to the foetus.

Talk to your doctor if you are breastfeeding your baby. Women who are HIV-positive must not breastfeed because HIV infection can be passed on to the baby in breast milk.

The ingredients in DAMICAVA can pass into your breast milk.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking DAMICAVA.

Driving and using machines:

The effect of DAMICAVA on the ability to drive vehicles or operate machinery is not known. DAMICAVA may affect your ability to drive and use machines.

You should not drive and use machines unless you know how DAMICAVA affects your abilities to do so.

It is not always possible to predict to what extent DAMICAVA 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 DAMICAVA affects them.

DAMICAVA contains mannitol

DAMICAVA contains mannitol which may have a mild laxative effect and interfere with the control of your blood sugar if you have diabetes mellitus.

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

3. How to take DAMICAVA

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

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

The usual dose is one tablet once daily, with or without food.

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

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

If you take more DAMICAVA 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 DAMICAVA

If you missed a dose of DAMICAVA, you should take DAMICAVA as soon as possible, provided the next dose is not due within 4 hours. If the next dose is due within 4 hours, you should not take the missed dose and simply resume the usual dosing schedule.

4. Possible side effects

DAMICAVA can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth, tongue or throat, which may cause difficulty in swallowing or breathing,

- rash or itching,
- fainting.

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

- Liver problems, indicated by yellowing of skin and eyes, dark urine.
- Heart problems may be indicated by chest pain.

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

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:

- allergic reaction
- extreme loss of weight or weight gain
- sleep disorder
- sleeplessness (insomnia)
- headache
- dizziness
- nausea
- diarrhoea
- vomiting
- abdominal distension (swelling)

- stomach pain or discomfort
- indigestion
- feeling tired (fatigue)
- lack of energy and enthusiasm (lethargy)
- fever (high temperature)
- general feeling of discomfort, illness or unease (malaise)
- wind (Flatulence)
- joint pain
- abnormal dreams
- nightmare
- feeling drowsy
- muscle disorders
- loss of body hair
- depression
- anxiety
- cough
- irritated or runny nose.

Frequent side effects that may show up in blood tests are:

- an increase in the level of liver enzymes.

Less frequent:

- inflammation of the liver (hepatitis)
- suicidal thoughts and behaviours (particularly in patients who have had depression or mental health problems before).

Less frequent side effects that may show up in blood tests:

- abnormally low count of a type of white blood cell (neutropenia)
- decreased number of red blood cells (anaemia)
- low levels of blood platelets (thrombocytopenia).

Frequency unknown:

- inflammation of the pancreas (pancreatitis)
- breakdown of muscle tissue
- liver failure (signs may include yellowing of the skin and the whites of the eyes or unusually dark urine)
- numbness, tingly feelings in the skin (pins and needles)
- sensation of weakness in the limbs
- 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)
- lactic acidosis (excess lactic acid in the blood).

Frequency unknown side effects that may show up in blood tests are:

- increase in an enzyme called amylase
- a failure of the bone marrow to produce new red blood cells (pure red cell aplasia).

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 “**Adverse drug reaction and quality problem reporting form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problemreporting-form/> or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of DAMICAVA.

5. How to store DAMICAVA

Store in the original container at or below 30 °C.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the container.

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 DAMICAVA contains

- The active substances are abacavir sulfate equivalent to abacavir 600 mg, dolutegravir sodium equivalent to dolutegravir 50 mg and lamivudine 300 mg as active ingredients.
- The other ingredients are magnesium stearate, mannitol, microcrystalline cellulose, povidone and sodium starch glycollate. The Opadry II Complete System 85F565121 Brown film-coating is made up of iron oxide red, iron oxide yellow, macrogol, polyvinyl alcohol (partly hydrolysed), talc and titanium dioxide.

What DAMICAVA looks like and contents of the pack

DAMICAVA tablets are brown coloured, oval shaped, biconvex, film-coated tablet, debossed with “Cipla” on one side and plain on other side.

DAMICAVA tablets are marketed in packs of 30's in white HDPE containers fitted with child resistant caps that contain a heat seal liner and 2 g silica gel bags.

Holder of certificate of registration

CIPLA MEDPRO MANUFACTURING (PTY) LTD.

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