

Emtricitabine / tenofovir disoproxil
fumarate, 200 mg / 300 mg (film-coated
tablets)

PATIENT INFORMATION LEAFLET FOR
DIDIVIR

SCHEDULING STATUS: **S4**

DIDIVIR 200 mg / 300 mg, film-coated tablets

Emtricitabine / tenofovir disoproxil

Contains sugar: Lactose monohydrate 87 mg

Read all of this leaflet carefully before you start taking DIDIVIR

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

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1. What DIDIVIR is and what it is used for

DIDIVIR (emtricitabine and tenofovir disoproxil fumarate) belongs to a class of medicine known as antiviral medicines.

DIDIVIR is indicated for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults and children age 12 years and older and is always used in combination with other anti-HIV medication.

To help reduce the risk of getting HIV-1 infection in adults who are HIV-negative, DIDIVIR must be used in combination with safer sex practices and rigorously precise use at all times. This is called Pre-Exposure Prophylaxis or Pr-EP.

WARNINGS:

DIDIVIR may lead to serious problems with your liver or cause too much lactic acid in your blood. If left untreated, this may even cause death.

The safety and efficacy of DIDIVIR in patients who are infected with both human immunodeficiency virus (HIV) and hepatitis B virus (HBV) have not been established. You should not use DIDIVIR for the treatment of a chronic HBV infection. You should be closely monitored by your doctor for several months if you are infected with HBV and discontinue the use of DIDIVIR.

Do not take DIDIVIR to reduce the risk of getting HIV-1 unless you are confirmed to be HIV-negative.

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2. What you need to know before you take DIDIVIR

Do not take DIDIVIR:

- if you are hypersensitive (allergic) to emtricitabine, tenofovir disoproxil fumarate or any of the other ingredients contained in DIDIVIR (listed in **section 6**).
- if you are pregnant or breastfeeding (see “**Pregnancy, breastfeeding and fertility**”).
- if you have kidney problems, kidney failure or are on dialysis.
- if you are already taking any other medicines containing tenofovir or emtricitabine or lamivudine, as these medicines contain the same or similar active ingredients as DIDIVIR.
- if you are a woman taking DIDIVIR to prevent HIV infection and become pregnant while taking DIDIVIR.
- if you do not know your HIV infection status or if you already have HIV-1 infection as you need to take other medicines together with DIDIVIR to treat HIV-1.
- if you are not fully committed to use DIDIVIR **every day** for the prevention of HIV infection.

See the section under “**What DIDIVIR is and what it is used for**” and talk to your healthcare provider for more information about how to prevent HIV infection.

Warnings and precautions

Take special care with DIDIVIR:

- if you have liver problems including hepatitis B or C virus infection
 - if you have any kidney disease or reduced kidney function or you are on dialysis.
 - if you are taking other medicines as DIDIVIR may interact with these other medicines.
- These medicines include antiretrovirals such as lamivudine, zidovudine, abacavir sulphate and co-formulations, didanosine, atazanavir and lopinavir/ritonavir.

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- if you suffer from bone disease, including previous fractures and low bone mineral density (osteopenia).
- if you have any other medical conditions.
- if you are older than 65 years.
- are also infected with the Hepatitis B or C Virus (HBV or HCV) as you need to be closely monitored as other HIV treatment might be considered.

Lactic acidosis

Some antiretrovirals, including DIDIVIR, may cause a condition known as lactic acidosis, together with an enlarged liver. Lactic acidosis, if it occurs, usually develops after a few months. Symptoms of lactic acidosis include deep, rapid breathing, drowsiness, and non-specific symptoms, such as nausea, vomiting and stomach pain. If you are female, obese, suffer from liver disease, or if you have been using antiretrovirals for a long time, you have a greater risk of developing this condition. Your treating doctor will monitor you closely for the development of lactic acidosis. Please report any of the symptoms listed here to him/her.

Pancreatitis

Antiretrovirals such as DIDIVIR may cause pancreatitis which may lead to abdominal pain, nausea or vomiting. Do not continue with DIDIVIR treatment before your doctor confirms that you do not have pancreatitis.

Immune reconstitution syndrome (IRIS)

Antiretroviral medicines, including DIDIVIR, can lead to changes in your immune system, this is referred to as Immune Reconstitution Syndrome (IRIS). Your immune system may get stronger

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and start fighting infections that were previously hidden. Tell your doctor if you notice any untoward symptoms after initiating DIDIVIR treatment.

Redistribution of body fat

Changes in body fat have been observed in patients taking antiretroviral medicines such as DIDIVIR. Body fat may accumulate around your upper back and neck area (buffalo-hump), breasts and trunk. Loss of fat around your limbs and face may occur. The cause and long-term effect of these conditions are unknown.

Patients with hepatitis B or C virus infection

DIDIVIR is not indicated for the treatment of hepatitis B or C Virus (HBV or HCV) infection. If you suffer from both HBV and HIV infection, you need to discuss this with your treating doctor before you start using DIDIVIR. If you have liver disease or cirrhosis (degenerations of liver cells and inflammation of liver tissue), it is not recommended to discontinue your antiretroviral treatment for hepatitis B or C if you are using it together with DIDIVIR. This may lead to liver failure or worsening of liver disease.

If you suffer from impaired kidney function, your doctor may decide to alter your dosage intervals or to use a different medication. DIDIVIR should be avoided with concurrent or recent use of medicines that are toxic to your kidneys for example tacrolimus.

Your kidneys primarily eliminates emtricitabine and tenofovir, therefore DIDIVIR in combination with other medicines that reduce kidney function, may alter this effect. Examples of such

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medicines are adefovir dipivoxil, cidofovir, acyclovir, valacyclovir, ganciclovir and valganciclovir for the treatment of Hepatitis B or C virus (HBV or HCV) or cytomegalovirus.

Osteonecrosis

If you have a history of previous fractures not due to trauma or are at risk of developing, osteonecrosis, osteopenia, osteoporosis or bone loss or osteomalacia (softening of bones) your doctor will regularly monitor your bone mineral density and may decide to supplement your diet with calcium and vitamin D. If you experience joint aches and pain, joint stiffness, difficulty in movement, bone pain or pain in your limbs, or muscle pain or weakness seek advice from your doctor.

Mitochondrial dysfunction following exposure in utero

Children exposed to nucleotide and nucleoside analogues such as DIDIVIR prior to or after birth should have clinical and laboratory follow up and should be fully investigated for possible mitochondrial dysfunction (disorder of the mitochondriae which generates energy for every cell in your body). Other indicators of mitochondrial dysfunction include blood disorders and dysfunctions of the nerves, which may cause numbness or weakness.

Using DIDIVIR for treatment of HIV infection

You must continue with DIDIVIR therapy in order to control your HIV infection and to reduce HIV-related illnesses.

DIDIVIR does not cure HIV infections. If you are HIV positive and take DIDIVIR with/without other anti-retroviral medicines, you may develop resistance to DIDIVIR. This means that your HIV infection may become harder to treat.

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DIDIVIR does not lessen your chance of passing HIV to other people through sex, sharing needles or being exposed to your blood. You must always practise safe sex and take appropriate measures for the sake of your health and the health of others.

Your HIV condition makes you prone to opportunistic infections even with the use of DIDIVIR. These may include respiratory infections (such as TB, pneumonia, flu-like, coughing) or cold sores.

Important information to know before taking DIDIVIR for prevention of HIV infection:

- **You must get tested to show that you are HIV negative.** It is necessary to get tested every 3 months to reaffirm your status. It is also important to know the status of your partner. Ask him/her to get tested too.
- Regular testing for other sexual transmitted infections that can enable HIV transmission such as syphilis and gonorrhoea.
- **Practise safe sex at all times. Never have any kind of sex without protection.** Always use a protective barrier such as condoms to minimise chances of coming into contact with bodily secretions such as blood, vaginal secretions and semen.
- You should not use DIDIVIR if you are not fully committed to use it **every day** for the prevention of HIV infection.
- **You must also use other prevention methods to keep from getting HIV.**
- Have fewer sexual partners.
- Seek information that will help you to reduce risky sexual behaviour.

If you take DIDIVIR to help reduce the risk of getting HIV-1 infection, you must get tested to make sure that you do not already have HIV-1 infection due to the fact that you can develop resistance.

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It is important to stay HIV-negative and to continue using safer sex practices while you are taking DIDIVIR to reduce the risk of HIV-1 infection. If you do become HIV-positive, you need more medicine than DIDIVIR alone to treat HIV-1.

Do not miss a dose of DIDIVIR. Forgetting to take your medicine will put you at risk of getting HIV.

Tell your healthcare professional if you have experienced any of these symptoms a month before you started taking DIDIVIR, or whilst taking DIDIVIR:

- tiredness
- fever
- increased sweating, especially at night
- rash
- vomiting
- diarrhoea
- joint or muscle aches
- headaches
- sore throat
- enlarged lymph nodes in the neck or groin areas

These symptoms may indicate signs of HIV infection.

You must also tell your doctor if you suspect that you were recently exposed to HIV. If you are taking DIDIVIR for prevention of HIV infection, your doctor may stop your therapy with DIDIVIR until your HIV status has been confirmed.

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Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. You should not take DIDIVIR if you are already taking other medicines containing emtricitabine, tenofovir disoproxil, tenofovir alafenamide, or other cytidine analogues, such as lamivudine. You should tell your doctor if you are receiving other medicines which may damage your kidneys.

Other infections

You may develop opportunistic infections or other conditions that may occur with HIV infections. Opportunistic infections are infections that happen when your immune system is weak. Some of these infections are different forms of Tuberculosis (TB) and some forms of pneumonia, Herpes Virus and a form of meningitis (an infection of the protective layers of the brain).

Children and adolescents

DIDIVIR is not for use in children under 12 years of age and children older than 12 years and weigh less than 35 kg.

Other medicines and DIDIVIR

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

In particular tell your doctor, if you are taking:

- didanosine-containing medication as tenofovir (component of DIDIVIR) may increase the level of didanosine in your blood and you will therefore have to be carefully monitored.

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- atazanavir or lopinavir and ritonavir coformulation as the tenofovir (component of DIDIVIR) level in your blood may increase, which may result in more side-effects. You will therefore have to be carefully monitored. DIDIVIR may decrease the amount of atazanavir sulphate in your blood. If you are taking DIDIVIR and atazanavir sulphate together, you should also be taking ritonavir.
- ledipasvir and sofosbuvir or sofosbuvir and velpatasvir, or sofosbuvir/velpatasvir/voxilaprevir co-formulation or adefovir dipivoxil. These medicines used for a liver disease, called hepatitis C or B, may increase the amount of tenofovir DF (a component of DIDIVIR) in your blood, which could result in more side effects.
- emtricitabine or tenofovir separately, lamivudine and zidovudine coformulation, lamivudine for HIV, lamivudine for HBV, abacavir sulphate and lamivudine coformulation, and abacavir sulfate, lamivudine and zidovudine coformulation, as DIDIVIR should not be combined with these medicines.
- Adefovir dipivoxil, cidofovir, acyclovir, valacyclovir, ganciclovir, valganciclovir, and tacrolimus, as co-administration of DIDIVIR with these medicines may alter your blood concentrations of the active ingredients in DIDIVIR.

Keep a complete list of all the medicines you take and give copies to your healthcare providers and pharmacist.

DIDIVIR with food, drink and alcohol

DIDIVIR can be taken without regard to meals.

Take DIDIVIR at the same time each day.

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Pregnancy, breastfeeding and fertility

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 DIDIVIR.

The safe use of DIDIVIR during pregnancy and breastfeeding has not been established. You should not use of DIDIVIR during pregnancy (see **section 2**).

A reliable method of contraception should be used to avoid pregnancy while taking DIDIVIR.

If you are HIV-infected you should not breastfeed your infant, to avoid risking transmission of HIV to your baby after birth. It is not known whether the active ingredients in DIDIVIR are excreted in human milk. **Because of both the potential for HIV transmission and the potential for serious adverse reactions in breastfed babies, you should not breastfeed your babies when using DIDIVIR.**

Driving and using machines

DIDIVIR can make you feel dizzy. If you develop such symptoms, you should avoid driving or operating machinery.

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

DIDIVIR contains lactose monohydrate.

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DIDIVIR contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take DIDIVIR

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

Always take DIDIVIR exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is one tablet once a day with or without food. Take DIDIVIR at the same time every day.

Tell your doctor if you have kidney problems so the dose of DIDIVIR can be altered.

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

Treatment of HIV:

If you are taking DIDIVIR for the treatment of HIV infection, you should take it in combination with other antiretroviral medicines.

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Prevention of HIV:

If you are taking DIDIVIR for reducing the risk of HIV infection, you must also use other preventative methods that can reduce the risk of getting HIV (e.g. condoms) (see **Warnings and precautions**).

If you take more DIDIVIR than you should

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

If you forget to take DIDIVIR

Always take DIDIVIR as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next day, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for the forgotten individual dose. It is important to take DIDIVIR regularly, because irregular intake may increase the risk of the virus developing resistance to your medication.

4. Possible side effects

DIDIVIR can have side effects.

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

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

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

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

- stomach discomfort, diarrhoea, fast shallow breathing, general feeling of discomfort, muscle pain or cramping, nausea, shortness of breath, sleepiness, and unusual tiredness or weakness, as these are symptoms associated with the development of lactic acidosis (see **Warnings and precautions**)
- less urine than is normal for you,
signs of serious liver problems e.g. jaundiced (yellow discolouration of the skin and/or white part of the eyes), if your urine turns dark and your stools become light, if you lose your appetite for several days or longer or if you develop stomach pain, since DIDIVIR may cause inflammation of your liver.

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:

- stomach ache
- joint pain, muscle aching or cramping, muscle pain or stiffness, pain in joints, swollen joints, back pain

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- weakness in arms, hands, legs or feet
- increased cough
- sore throat, runny and itchy nose and sneezing
- excess gas (wind)
- diarrhoea
- headache
- nausea (feeling sick), vomiting
- dizziness
- sleep disturbances (including abnormal dreams and sleeplessness)
- stomach discomfort, belching, passing of gas, heartburn, indigestion Rashes, (including red spots or blotches sometimes with blistering and swelling of the skin which may be allergic reactions), itching, changes in skin discolouration including darkening of the skin in patches
- difficulty breathing

Blood tests may also show:

- low white blood cell count (a reduced white blood cell count can make you more prone to infection)
- increased triglycerides (fatty acids), bile or sugar in the blood
- increased enzymes that helps with the metabolism of sugars and fats
- increased liver enzymes.
- increased creatine kinase (an enzyme resulting from breakdown of your muscles)

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Less frequent side effects:

- joint or muscle pain
- tingling feelings like pins and needles
- back pain caused by kidney problems
- anaemia (low red blood cell count), which may include symptoms e.g. fatigue, skin pallor, shortness of breath, light-headedness, dizziness, or a fast heartbeat
- breakdown of muscle, muscle pain or weakness which may occur due to damage to the kidney tubule cells
- inflammation of the pancreas which most commonly begins with abdominal pain in the middle or upper left part of the abdomen and may increase after eating or lying flat the back
- fatty liver disease

Blood and urine tests may also show:

- decreases in potassium in the blood
- changes to your urine.
- decreases in phosphate in the blood
- increased creatinine in your blood
- decreases in phosphate in the blood

Side effects with unknown frequency:

- loss of bone mass
- blood in the urine
- trouble sleeping

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- nervousness
- mood disturbances (depression)
- chest pain
- lung infection (e.g. pneumonia)
- inflammation of the pancreas which most commonly begins with abdominal pain in the middle or upper left part of the abdomen and may increase after eating or lying flat the back
- increased liver enzymes
- kidney problems
- fever
- sweating
- weight loss.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse reactions to SAHPRA via Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Cipla Medpro (Pty) Ltd. by email: drugsafety@cipla.com or telephone: 080 222 6662 (toll free).

5. How to store DIDIVIR

Store at or below 30 °C.

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Do not use if the seal over bottle opening is broken or missing.

KEEP THIS MEDICINE OUT OF REACH OF CHILDREN.

Keep the container in the outer carton.

Keep the container tightly closed.

Do not use the medication 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, for example toilets.

6. Contents of the pack and other information

What DIDIVIR contains

The active substances are emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg.

The other ingredients are croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinised starch, opadry blue (FD&C Blue #2 / Indigo carmine AL 3-5%, hypromellose, lactose monohydrate, titanium dioxide, and triacetin).

What DIDIVIR looks like and contents of the pack

Blue coloured, capsule-shaped, biconvex, film-coated tablets plain on both sides.

DIDIVIR is packed in a HDPE container with a non-child resistant cap and a silica gel bag desiccant.

Pack sizes: 30.

Holder of certificate of registration

CIPLA MEDPRO MANUFACTURING (PTY) LTD.

1474 South Coast Road

Emtricitabine / tenofovir disoproxil
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tablets)

Mobeni

Durban

4052

Customer Care: 080 222 6662

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Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER:

The QR Code to
be generated and
included after
approval.