

Module 1.3.2: Patient Information Leaflet

Information for the Patient about

MIVUTEN

Read all of this leaflet carefully before you start taking MIVUTEN.

- **Keep this leaflet; you may need to read it again.**
- **If you have further questions, please ask your doctor or your pharmacist.**
- **MIVUTEN 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.**

SCHEDULING STATUS:

S4

PROPRIETARY NAME (AND DOSAGE FORM):

MIVUTEN (Tablets)

WHAT MIVUTEN CONTAINS:

The active substances are lamivudine and tenofovir. Each **MIVUTEN** tablet contains lamivudine 300 mg and 245 mg of tenofovir disoproxil in the form of 300 mg tenofovir disoproxil fumarate.

The inactive ingredients include corn starch, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and polysorbate 80.

Contains lactose.

WARNING:

MIVUTEN may cause serious liver damage or too much acid in your blood. This may result in death if left untreated. Report to your doctor immediately if you develop nausea, vomiting, stomach pain, loss of appetite, generally feel unwell or develop rapid or shallow breathing. This condition may develop after a few or several months of treatment.

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

WHAT MIVUTEN IS USED FOR:

MIVUTEN belongs to a group of antiviral medicines, called reverse transcriptase inhibitors.

MIVUTEN is used to treat Human Immunodeficiency Virus (HIV) infection in adults over 18 years of age.

BEFORE YOU TAKE MIVUTEN:

Do NOT take MIVUTEN if you:

- Are allergic (hypersensitive) to lamivudine or tenofovir, or any of the other ingredients in **MIVUTEN**.
- Have moderate to severe impairment of kidney function.
- Are pregnant or breastfeeding.

- Are younger than 18 years of age.
- Are taking zalcitabine (see "**Taking other medicines with MIVUTEN**").

Take special care with MIVUTEN:

MIVUTEN may cause a serious, and life-threatening, side-effect known as lactic acidosis (excess of lactic acid in your blood), together with an enlarged liver (see initial boxed "**WARNING**" and "**POSSIBLE SIDE-EFFECTS**"). Early symptoms include deep, rapid breathing, drowsiness, and non-specific symptoms, such as nausea, vomiting and stomach pain. This rare, but serious, side-effect has occasionally been fatal. Lactic acidosis occurs more often in women, particularly if they are very overweight. If you have liver disease you may also be more at risk of getting this condition. While you are being treated with **MIVUTEN**, please report any of these symptoms to your doctor as a matter of urgency.

MIVUTEN should not be used to treat hepatitis B virus (HBV) infection (see initial boxed "**WARNING**").

MIVUTEN may cause impairment of kidney function (see "**POSSIBLE SIDE-EFFECTS**"). Please report to your doctor immediately if you develop swelling of the lower limbs, hands, body or face, are short of breath and if you pass very little or no urine. You may have to go for regular blood tests to monitor your kidney function.

Redistribution, accumulation, or loss of body fat may occur in patients receiving **MIVUTEN**. You may develop excess fat on your abdomen (stomach), behind your neck, or your breasts may enlarge, while your legs and arms become thinner.

Contact your doctor as soon as possible if you notice changes in body fat distribution. You may require blood tests to monitor your cholesterol and blood sugar (glucose) levels.

Treatment with **MIVUTEN** may cause inflammation of the pancreas (pancreatitis) (see "**POSSIBLE SIDE-EFFECTS**"). You must report to your doctor as a matter of urgency if you develop severe stomach pain or cramps accompanied by fever, chills, and severe nausea and vomiting.

MIVUTEN is not a cure for HIV infection. While taking **MIVUTEN** you may still develop infections or other illnesses associated with HIV infection.

MIVUTEN does not reduce the risk of passing HIV to others through sexual contact or contamination with blood. Therefore, it is important to continue to take appropriate precautions to prevent passing HIV to others.

You may develop signs and symptoms of inflammation from previous infections soon after treatment with **MIVUTEN** is started. It is believed that these symptoms are due to an improvement in the body's immune response, causing inflammation in response to infections that may have been present with no obvious symptoms. If you notice any symptoms of infection, please inform your doctor immediately.

While taking **MIVUTEN**, you may develop a decrease in bone mineral density of the hip and spine (your hip and spine may become brittle). However, this is not associated with an increased risk of fracture. Your doctor will monitor you for this

possible side-effect and may decide to prescribe a calcium and vitamin D supplement for you.

Please report to your doctor as soon as possible if you experience stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. These symptoms may be due to a bone disease called osteonecrosis (loss of blood supply to the bone).

Taking MIVUTEN with food and drink:

MIVUTEN should be taken with food.

Pregnancy and breastfeeding:

Do not take **MIVUTEN** if you are pregnant or breastfeeding your baby. If you are pregnant, or are planning to become pregnant, you must discuss alternative treatment with your doctor. If your doctor has prescribed **MIVUTEN**, you should make use of effective contraception.

Mothers should not breastfeed their infants while taking **MIVUTEN**. In general, women infected with HIV should not breastfeed their infants in order to avoid transmission of HIV to their babies.

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

Driving and using machinery:

MIVUTEN may cause dizziness. If you feel dizzy while taking **MIVUTEN**, do not drive and do not use any tools or machines.

Important information about some of the ingredients of MIVUTEN:

MIVUTEN contains lactose. If you have been diagnosed with glucose-galactose malabsorption, hereditary galactose intolerance or the Lapp lactase deficiency, do not take **MIVUTEN**.

Taking other medicines with MIVUTEN:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, concomitant use of such medicines with MIVUTEN may cause undesirable interactions. Please consult your doctor or pharmacist, or other healthcare professional for advice.

Do not take **MIVUTEN** with any other medicines containing lamivudine, tenofovir disoproxil fumarate, adefovir dipivoxil, didanosine, or zalcitabine (see "**Do NOT take MIVUTEN if you**").

Please inform your doctor if you are taking any of the following medicines, since you may require a dosage adjustment or special precaution:

- Abacavir, atazanavir, darunavir, lopinavir, or ritonavir to treat HIV infection.
- Any of the following antibiotics: co-trimoxazole, pentamidine, vancomycin.
- Antibiotics from the aminoglycoside class.
- Amphotericin B for fungal infections.
- Interleukin-2 for certain cancers.

- Tacrolimus to suppress the immune system.

HOW TO TAKE MIVUTEN:

Always take **MIVUTEN** exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are not sure.

Do not share medicines prescribed for you with others.

The usual dose is one **MIVUTEN** tablet once daily with food.

Your doctor will decide how long treatment with **MIVUTEN** will last. Do not stop taking **MIVUTEN** without discussing it with your doctor.

If you have the impression that the effect of **MIVUTEN** is too strong or too weak, please discuss this with your doctor.

If you take more MIVUTEN than you should:

Always take **MIVUTEN** exactly as your doctor has instructed you. In the event of an overdose, or if someone else has taken your medicine by mistake, you, or this other person, may experience side-effects such as those listed below. **In the event of overdose, consult your doctor or pharmacist. If neither is available, immediately seek help at the nearest hospital or poison control centre.**

If you forget to take MIVUTEN:

It is important that you do not miss any doses. If you miss a dose of **MIVUTEN**, take it as soon as possible. If it is almost time for your next dose, skip the missed dose

and go back to your regular dosing schedule of one tablet once daily. Do not take a double dose to make up for a forgotten individual dose.

POSSIBLE SIDE-EFFECTS:

MIVUTEN can cause side-effects.

Not all side-effects reported for MIVUTEN are included in this leaflet. Should your general health worsen while taking MIVUTEN, please consult your doctor, pharmacist or other healthcare professional for advice.

Serious side-effects that you, or a family member, should report to your doctor as a matter of urgency include:

- Those that occur frequently:
 - Any skin rash.
 - Severe coughing with the production of yellow, green, or brown phlegm, with shortness of breath and/or chest pain.
- Those that occur less frequently:
 - Severe swelling of the face, lips, tongue, or whole body.
 - Fever, chills, bleeding from the gums or pinpoint red spots on the skin, sore throat, coughing with sputum production, and pallor with chest pain.
 - Deep, rapid breathing, drowsiness, and non-specific symptoms, such as nausea, vomiting and stomach pain (see **"Take special care with MIVUTEN"**).
 - Severe stomach pain or cramps accompanied by fever and chills (see **"Take special care with MIVUTEN"**).

- Yellow discolouration of the skin or whites of the eyes with pain over the liver area and loss of appetite.
- Those that occur with unknown frequency:
 - Hives, itching, skin rash or any other symptom you think may be due to an allergic reaction.

Other side-effects that you should report to your doctor as soon as possible include:

- Those that occur frequently:
 - Dizziness.
 - Pins and needles in the hands or feet, or burning, intractable pain in the limbs.
- Those that occur less frequently:
 - Abnormal distribution of fat (see **"Take special care with MIVUTEN"**).

Side-effects that you should report to your doctor if they continue or become bothersome include:

- Those that occur frequently:
 - Headache, sleeplessness.
 - Cough, or runny or blocked nose.
 - Loose stools (diarrhoea).
 - Indigestion, flatulence or distension of the stomach.
 - Hair loss.
 - Muscle or joint pain.
 - Fatigue.
 - Weight loss or loss of appetite.

- Anxiety or depression.
- Sweating.
- Back pain.

Please tell your doctor or pharmacist of any undesirable effects you think may be due to **MIVUTEN**, especially if not mentioned in this leaflet.

STORING AND DISPOSING OF MIVUTEN:

Store at or below 30 °C. Keep container tightly closed.

Do not use the medicine 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.

KEEP THIS MEDICINE OUT OF REACH OF CHILDREN.

PRESENTATION OF MIVUTEN:

White, cylindrical HDPE bottle closed with a white opaque HDPE non child resistance cap with a white opaque liner, containing 28 or 30 tablets.

IDENTIFICATION OF MIVUTEN:

Capsule-shaped, bilayered, biconvex, film-coated tablets with one layer orange and the other layer white in colour, "LT" debossed on one side with central break line and plain on the other side.

REGISTRATION NUMBER:

45/20.2.8/0108

NAME AND ADDRESS OF THE HOLDER OF THE CERTIFICATE OF

REGISTRATION:

CIPLA MEDPRO (PTY) LTD

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DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET:

14 September 2012