TENOHOPE E (EMTRICITABINE 200MG & TENOFOVIR DISOPROXIL FUMARATE 300MG TABLETS)

Tenofovir Disoproxil Fumarate/Emtricitabine (300mg/200mg)

What is in this leaflet

What *Tenohope-E* is used for

Tenohope-E is indicated in combination with other antiretroviral agents for the treatment of HIV-1 in adults.

How *Tenohope-E* works *Tenohope-E* tablet contains two active substances, emtricitabine and tenofovir disoproxil. Both of these active substances are antiretroviral medicines which are used to treat HIV infection. Emtricitabine is a nucleoside reverse transcriptase inhibitor and tenofovir is a nucleotide reverse transcriptase inhibitor. However, both are generally known as NRTIs and they work by interfering with the normal working of an enzyme (reverse transcriptase) that is essential for the virus to reproduce itself.

Before you use *Tenohope-E*

- *When you must not use it*

Do not take *Tenohope-E*

If you are allergic (hypersensitive) to emtricitabine, tenofovir, tenofovir disoproxil fumarate, or any of the other ingredients of *Tenohope-E* listed at the end of this leaflet. If this applies to you, tell your doctor immediately.

- *Before you start use it*

Tell your doctor if you have had kidney disease, or if tests have shown problems with your kidneys. *Tenohope-E* may affect your kidneys. Before starting treatment, your doctor may order blood tests to assess kidney function. Your doctor may also order blood tests during treatment to monitor your kidneys and may advise you to take the tablets less often. *Tenohope-E* is not recommended if you have severe kidney disease or are receiving haemodialysis. *Tenohope-E* is not usually taken with other medicines that can damage your kidneys (see Taking other medicines). If this is unavoidable, your doctor will monitor your kidney function once a week.

Talk to your doctor if you are over 65. *Tenohope-E* has not been studied in patients over 65 years of age. If you are older than this and are prescribed Tenohope-E, your doctor will monitor you carefully.

Tenohope-E is not for use in children and adolescents under 18 years of age.

Talk to your doctor if you have a history of liver disease, including hepatitis.

Patients with liver disease including chronic hepatitis B or C, who are treated with antiretrovirals, have a higher risk of severe and potentially fatal liver complications. If you have hepatitis B infection, your doctor will carefully consider the best treatment regimen for you.

Both active substances in *Tenohope-E* show some activity against hepatitis B virus although emtricitabine is not approved for the treatment of hepatitis B infection. If you have a history of liver disease or chronic hepatitis B infection your doctor may conduct blood tests in order to carefully monitor liver function.

- *Taking other medicines*

You should not take *Tenohope-E* if you are already taking other medicines that contain the components of Tenohope-E, tenofovir disoproxil Fumarate and emtricitabine, or any other antiviral medicines that contain lamivudine or adefovir dipivoxil.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

It is especially important to tell your doctor if you are taking other medicines which may damage your kidneys.

These include:

- Aminoglycosides (for bacterial infection)
- Amphotericin B (for fungal infection)
- Foscarnet (for viral infection)
- Ganciclovir (for viral infection)
- Pentamidine (for infections)
- Vancomycin (for bacterial infection)
- Interleukin-2 (to treat cancer)
- Cidofovir (for viral infection)

Other medicines containing didanosine (for HIV infection): Taking *Tenohope-E* with other antiviral medicines that contain didanosine can raise the levels of didanosine in your blood and may reduce CD4 cell counts. Rarely, inflammation of the pancreas and lactic acidosis (excess lactic acid in the blood), which sometimes causes death, have been reported when medicines containing tenofovir disoproxil fumarate and didanosine were taken together.

Your doctor will carefully consider whether to treat you with combinations of tenofovir and didanosine.

How to use *Tenohope-E*

- *How much to use*

The dosage of *Tenohope-E* is one tablet once daily taken orally with or without food.

- *When to use it*

Use as directed by your doctor or pharmacist.

- *How long to use it*

Do not stop your treatment without contacting your doctor.

- *If you forget to use it*

It is important not to miss a dose of Tenohope-E.

If you do miss a dose of *Tenohope-E* within 12 hours of when it is usually taken, take it as soon as you can, and then take your next dose at its

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regular time.

If it is almost time (less than 12 hours) for your next dose anyway, forget about the missed dose. Wait and take the next dose at the regular time. Do not take a double dose to make up for a forgotten tablet.

If you throw up less than 1 hour after taking *Tenohope-E*, take another tablet. You do not need to take another tablet if you were sick more than 1 hour after taking *Tenohope-E*.

- *If you use too much (overdose)*
If you accidentally take more than the recommended dose of *Tenohope-E*, contact your doctor or nearest emergency department for advice. Keep the tablet bottle with you so that you can easily describe what you have taken.

While you are using it

- *Things you must do*
Once you start taking *Tenohope-E*, look out for possible signs of lactic acidosis. Medicines containing nucleoside analogues, including *Tenohope-E*, can cause lactic acidosis (excess of lactic acid in your blood), together with an enlarged liver. Deep, rapid breathing, drowsiness, and non specific symptoms such as nausea, vomiting and stomach pain, might indicate the development of lactic acidosis. 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 *Tenohope-E*, your doctor will monitor you closely for any signs that you may be developing lactic acidosis.

Other precautions
Combination antiretroviral therapies (including *Tenohope-E*) may raise blood sugar, increase blood fats (hyperlipaemia), cause changes to body fat, and resistance to insulin.

If you are diabetic, overweight or have high cholesterol, talk to your doctor.
Look out for infections. If you have advanced HIV infection (AIDS) and have an infection, you may develop symptoms of infection and inflammation or worsening of the symptoms of an existing infection once treatment with *Tenohope-E* is started. These symptoms may indicate that your body's improved immune system is fighting infection. Look out for signs of inflammation or infection soon after you start taking *Tenohope-E*. If you notice signs of inflammation or infection, tell your doctor at once.

Bone problems.
Some patients taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). The length of combination antiretroviral therapy, corticosteroid use, alcohol consumption, severe Immunosuppression, higher body mass index, among others, may be some of the many risk factors for developing this disease. Signs of osteonecrosis are joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms inform your doctor. Bone problems (sometimes resulting in fractures) may also occur due to damage to kidney tubule cells (see section 6, Side effects).

Stopping treatment with *TENOHOPE-E* may reduce the effectiveness of the anti-HIV therapy recommended by your doctor. Speak with your doctor before you stop taking *TENOHOPE-E* for any reason, particularly if you are experiencing any side effects or you have another illness. Contact your doctor before you restart taking *TENOHOPE-E*.

If you have HIV infection and hepatitis B, it is especially important not to stop your *TENOHOPE-E* treatment without talking to your doctor first. Some patients have had blood tests or symptoms indicating that their hepatitis has got worse after stopping *TENOHOPE-E*. You may require blood tests for several months after stopping treatment. In some patients with advanced liver disease or cirrhosis, stopping treatment is not recommended as this may lead to worsening of your hepatitis.

Tell your doctor immediately about new or unusual symptoms after you stop treatment, particularly symptoms you associate with hepatitis B infection.

- *Things you must not do*
This medicine is not a cure for HIV infection. While taking *TENOHOPE-E* you may still develop infections or other illnesses associated with HIV infection.

You can also pass on the virus to others, so it is important to take precautions to avoid infecting other people.

- *Things to be careful of Pregnancy and breast-feeding* Ask your doctor or pharmacist for
advice before taking any medicine. You must not take *Tenohope-E* during pregnancy unless specifically discussed with your doctor. Although there are limited clinical data on the use of *Tenohope-E* in pregnant women, it is not usually used unless absolutely necessary.

If you are a woman who could get pregnant during treatment with *Tenohope-E*, you must use an effective method of contraception to avoid becoming pregnant.

If you become pregnant, or plan to become pregnant, ask your doctor about the potential benefits and risks of therapy with *Tenohope-E* to you and your child. If you have taken *Tenohope-E* during your pregnancy, your doctor may request regular blood tests and other diagnostic tests to monitor the development of your child. In children whose mothers took NRTI's during pregnancy, the benefit from the protection against HIV

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outweighed the risk of side effects.

Do not breast-feed during treatment with *Tenohope-E*. This is because the active substances in this medicine pass into human breast milk.

If you are a woman with HIV it is recommended that you do not breast-feed, to avoid passing the virus to the baby in breast milk.

Driving and using machines
Tenohope-E can cause dizziness. If you feel dizzy while taking Tenohope-E, do not drive and do not use any tools or machines.

Tell your doctor if you are lactose-intolerant or intolerant to other sugars. *Tenohope-E* contains lactose monohydrate. If you know you are lactose-intolerant, or if you have been told that you have intolerance to any other sugars, talk to your doctor before taking this medicine.

Side effects
Like all medicines, *Tenohope-E* can cause side effects, although not everybody gets them.

Tell your doctor about any of the following side effects:

Very common side effects
- dizziness, headache, diarrhoea, feeling sick (nausea), being sick (vomiting)
- muscle pain and weakness (if creatine kinase levels in the blood are increased)

Tests may also show:
- decreases in phosphate in the blood

Common side effects
- pain, stomach pain
- difficulty sleeping, abnormal dreams
- problems with digestion resulting in discomfort after meals, flatulence
- rashes (including red spots or blotches sometimes with blistering and swelling of the skin), which may be allergic reactions, itching, changes in skin colour including darkening of the skin in patches
- other allergic reactions, such as wheezing, swelling or feeling light-headed

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
- liver and pancreas problems

Rare side effects
- increased creatinine in your blood
- lactic acidosis (excess lactic acid in the blood, a serious side effect that can be fatal). The
- following side effects may be signs of lactic acidosis:
- deep rapid breathing
- drowsiness
- feeling sick (nausea), vomiting and stomach pain

If you think you may have lactic acidosis, contact your doctor at once. pain in the abdomen (tummy) caused by inflammation of the pancreas
- changes to your urine and back pain caused by kidney problems, including kidney failure

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Public→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of *Tenohope-E*

- *Storage*
- Keep out of the reach and sight of children.
- Do not store above 30°C.
- Store in the original container in order to protect from moisture.
- Keep the bottle tightly closed.
- Do not use *Tenohope-E* after the expiry date which is stated on the bottle and carton after {EXP}. The expiry date refers to the last day of that month.

- *Disposal*
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*
Blue colored, Capsule shaped, biconvex, film coated tablets, debossed with 'L 24' on one side of the tablet and plain on other side.

- *Ingredients*
- Active ingredients: Tenofovir Disoproxil Fumarate and Emtricitabine

- Inactive ingredients Microcrystalline cellulose, Pregelatinized Starch, Croscarmellose sodium, Lactose monohydrate, Colloidal Silicon Dioxide, Magnesium stearate, Instacoat Universal Blue

- *MAL number:*
MAL20016140AZ

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