PATIENT INFORAMTION LEAFLET

SCHEDULING STATUS

S4

RICOVIR (film-coated tablet)

Tenofovir disoproxil fumarate, 300 mg

Contains sugar: Lactose monohydrate 574,00 mg

RICOVIR may lead to serious problems with your liver or cause too much acid in your blood. If left untreated, this may even cause death. The safety and efficacy of RICOVIR in patients who are infected with both human immunodeficiency virus (HIV) and hepatitis B virus (HBV) have not been established. You should be closely monitored by your doctor for several months if you are infected with HBV.

Read all of this leaflet carefully before you start taking RICOVIR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- RICOVIR 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 RICOVIR is and what it is used for.

2. What you need to know before you take/ use RICOVIR**.**

3. How to take RICOVIR**.**

4. Possible side effects.

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1. What RICOVIR is and what it is used for

- RICOVIR belongs to a group of antiviral medicines, also known as antiretrovirals, called nucleotide reverse transcriptase inhibitors (NRTIs).
- These are used to treat Human Immunodeficiency Virus (HIV) infection.
- RICOVIR is used in combination with other antiretroviral medicines for the treatment of HIV infection.
- **Chronic Hepatitis B:**

  RICOVIR is indicated as monotherapy (single drug) in HIV uninfected patients for the treatment of chronic hepatitis B in adults 18 years of age and older with compensated liver disease, with evidence of active viral replication, persistent elevated ALT and histological evidence of active inflammation and/or fibrosis.

- **What you need to know before you take /use RICOVIR**

Do not take RICOVIR:

- If you are hypersensitive (allergic) to tenofovir or any of the ingredients in the RICOVIR tablets.
- If you are pregnant or breastfeeding (see *Pregnancy ,lactation and fertility*).
- If you have or had moderate to severe kidney problems (see **Take Special Care with RICOVIR**).

- If you are taking any other medicines containing tenofovir. disoproxil or adevofir dipivoxil (a medicine used to treat chronic hepatitis B).
- If you are younger than 18 years of age.
- **RICOVIR** should not be used in combination with the fixed-dose combination products containing emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg, or other fixed dose combination products that contain tenofovir DF, since it is an ingredient of these products.

Warnings and precautions

Take special care with RICOVIR:

Patients to be treated with RICOVIR for hepatitis B infection should be proven to be negative for HIV infection and should be tested regulary for HIV infection.

- If you have advanced HIV infection (AIDS).
- **Talk to your doctor or pharmacist if you have had kidney disease or if tests have shown problems with your kidneys**

  RICOVIR may affect your kidneys. Before starting treatment, your doctor may order blood tests to assess kidney function and may advise you to take RICOVIR tablet less often. Do not reduce the prescribed dose unless your doctor has told you to do so. Your doctor may also order blood tests during treatment to monitor how your kidneys work.
- **Take care not to infect other people**

  RICOVIR will not cure or prevent HIV infection or AIDS. However, it helps to keep HIV from reproducing and appears to slow down the destruction of the immune system. RICOVIR will not keep you from spreading HIV to other people through sexual contact or blood contamination. You must continue to use precautions to avoid this
- **Bone problems**

You may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone).

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, tell your doctor.

- If you have a history of bone fractures which occurs without trauma or if your bones are weak but not so far gone that they break easily (osteopenia).
- **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 for you. If you have a history of liver disease or chronic hepatitis B infection, your doctor may conduct blood tests to monitor your liver function.

  If you are co-infected with HIV and HBV and stop taking RICOVIR, you should be monitored closely.
- **Look out for signs of possible lactic acidosis (**excess of lactic acid in your blood) once you start taking RICOVIR. *Possible signs of lactic acidosis are:*

- deep, rapid breathing;
- drowsiness;
- nausea, vomiting and stomach pain.

  This side effect can cause enlargement of the liver and has occasionally been fatal.

  Lactic also occurs more often in women, particularly if they are overweight. If you have liver disease, you may also be more at risk of getting this condition. While you are being treated with RICOVIR, your doctor will monitor you closely for any signs that you may be developing lactic acidosis.

- **Metabolic abnormalities**

In the treatment of HIV, combination antiretroviral therapy (including RICOVIR) may change your body shape, by changing the way body fat is distributed. You may lose fat from your legs, arms and fact; gain fat around the tummy (abdomen) and internal organs; get larger breasts or fatty lumps on the back of the neck ("buffalo hump"). The cause and the long-term effects of these changes are not known.

- **Look out for infections**

  In some patients with advanced HIV infection (AIDS) and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms. If you notice any symptoms of infection, please tell your doctor at once.

- **Talk to your doctor or pharmacist if you have problems with your pancreas:**

  Look out for the symptoms of pancreatitis such as:

  - abdominal pain
  - nausea
  - vomiting

- If you are older than 65 years.

Children and adolessents

- Safety and effectiveness in children younger than 18 years of age have not been established.

Other medicines and RICOVIR:

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor, pharmacist or healthcare professional about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements.

Especially tell your doctor, pharmacist or healthcare professional if you take:

- aminoglycosides, pentamidine or vancomycin (for bacterial infection)
- amphotericin B (for fungal infection)
- foscarnet, ganciclovir or cidovir (for viral infection)
- interleukin-2 (to treat cancer)
- adefovir dipivoxil (for HBV)
- tacrolimus (for suppression of the immune system)
- didanosine (for HIV infection)
- non-steroidal anti-inflammatory medicines (NSAIDs)

Keep a complete list of all the medicines that you are taking. Make a new list when medicines are added or stopped. Give copies of this list to your doctor, pharmacist or healthcare professional **EVERY TIME** you visit them or fill a prescription.

RICOVIR with food and drink and alcohol

RICOVIR can be taken with or without a meal.

Pregnancy and breastfeeding and fertility:

Pregnancy:

You must not take RICOVIR during pregnancy.

If you are a woman who could become pregnant during treatment with RICOVIR, you must use an effective method of contraception to avoid becoming pregnant.

Breastfeeding:

It is not known whether RICOVIR passes into breastmilk. Breastfeeding is not recommended in patients with HIV infection because of the risk of passing the virus onto the breastfed infant.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning t ohave a baby please consult your doctor, pharmacist or other health care professional for advice before taking RICOVIR.

Driving and using machinery:

RICOVIR may cause dizziness. It is not always possible to predict to what extent RICOVIR 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 RICOVOR affects them.

RICOVIR contains lactose

RICOVIR tablets contain lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking RICOVIR.

2. How to take RICOVIR:

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

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

Adults

- The usual dose for adults of RICOVIR is one tablet each day without regard of food.
- **For the treatment of HIV-1 or chronic hepatitis B in adults:**

  The dose of RICOVIR (tenofovir disoproxil fumarate) is 300 mg once daily taken orally, without regard to food.

- **Chronic Hepatitis B**

  Safety and efficacy of RICOVIR in patients younger than 18 years of age have not been established.

- If you have kidney problems, your doctor may recommend that you take RICOVIR less frequently.
- Do not suddenly stop taking RICOVIR without consulting with your doctor first.
- If you have the impression that the effect of RICOVIR is too strong or too weak, talk to your doctor or pharmacist.

If you take more RICOVIR 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 your RICOVIR:

Do not take a double dose to make up for forgotten individual doses.

It is important that you do not miss any doses.

If you miss a dose of RICOVIR, take it as soon as possible and then take your next scheduled dose at its regular time.

If it is almost time for your next dose, do not take the missed dose. Wait and take the next dose at the regular time.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking RICOVIR:

- You should not stop treatment unless your doctor instructs you to. When your RICOVIR supply starts to run low, get more from your healthcare provider or pharmacy.

- This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time.
- The virus may develop resistance to RICOVIR and become harder to treat.

3. Possible side effects

RICOVIR can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing;
- skin rash or itching;
- fainting;
- fever
- severe tiredness or aches and pains or generally feeling ill.

Lactic acidosis (excess lactic acid in the blood) is manifested by:

- Feeling very weak or tired.
- Unusual (not normal) muscle pain.
- Trouble breathing.
- Stomach pain with nausea and vomiting.
- Feeling cold, especially in your arms and legs.
- Feeling dizzy or lightheaded.
- Fast or irregular heartbeat.

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

- chest pain
- yellow skin or eyes, itching, or pain in the abdomen (stomach) caused by inflammation of the liver
- pain in the abdomen (stomach), caused by inflammation of the pancreas (pancreatitis)
- numbness, tingling, or a burning sensation or weakness of hands and feet
- pneumonia

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:

- diarrhoea
- vomiting
- nausea
- feeling tired
- feeling bloated
- sweating
- headache

The following side effects have been reported less frequently:

- breakdown of muscle, muscle pain or weakness
- pain in the joints

- back pain
- blood disorders (will show up in blood tests)
- weight loss
- inability to sleep
- anxiety
- depression

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

Safety and effectiveness of RICOVIR in paediatric patients younger than 18 years of age or less than 35 kg with chronic hepatitis B have not been established.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "Report Drug Reaction Process", found online under SAHPRA's safety publications: https://www.sahpra.org.za/. By reporting side effects, you can help provide more information on the safety of RICOVIR.

4. How to store RICOVIR

- Store at or below 30 °C.
- Store in the original container.
- Protect from light.
- Do not use if seal over bottle opening is broken or missing.
- Do not remove from carton until required for use.

- Keep out of reach of children.
- Do not use after the expiry date stated on the label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Do not store in a bathroom.

5. Contents of the pack and other information

What RICOVIR contains:

- Each **RICOVIR** film-coated tablet contains:

  Tenofovir disoproxil fumarate 300 mg

  Contains sugar: Lactose monohydrate 574mg

- The other ingredients are: lactose monohydrate, magnesium stearate, microcrystalline cellulose, croscarmellose sodium, film-coat {hypromellose, titanium dioxide, Triacetin /glycerol triacetate, FD & C blue #2/indigo carmine aluminium lake}

What RICOVIR looks like and contents of the pack:

Light blue coloured, round biconvex film coated tablet debossed with ‘153’ on one side and ‘M’ on other side.

HDPE bottle of 30’s and HDPE bottle of 100’s.

Holder of Certificate of Registration and Manufacturer

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website