

RICOVIR TABLET

Tenofovir Disoproxil Fumarate (300mg)

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What *Ricovir tablet* is used for

Tenofovir disoproxil fumarate is the active substance in *Ricovir tablet*. This active substance is an antiretroviral or antiviral medicine which is used to treat Human Immunodeficiency Disease (HIV) infection for adults over 18 years of age.

How *Ricovir tablet* works

Ricovir tablet is a nucleotide reverse transcriptase inhibitor, generally known as an NRTI and works by interfering with the normal working of enzymes reverse transcriptase that are essential for the viruses to reproduce themselves.

This medicine is not a cure for HIV infection.

Before you use *Ricovir tablet*

- When you must not use it

If you are allergic to tenofovir, tenofovir disoproxil fumarate or any of the other ingredients of this medicine (listed in inactive ingredients). Talk to your doctor or pharmacist before taking *Ricovir tablet*.

- Before you start to use it

Ricovir tablet may affect your kidneys. Before starting treatment, your doctor may order blood tests to assess your kidney function and may advise you to take the tablets 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.

- *Ricovir tablet* 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.
- Some people with HIV taking combination antiretroviral therapy 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.
- Talk to your doctor if you have a history of liver disease, including hepatitis.
- People 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.

- Taking other medicines

- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
- Do not take *Ricovir tablet* if you are already taking other medicines containing tenofovir disoproxil fumarate.
- Do not take *Ricovir tablet* together with medicines containing adefovir dipivoxil (a medicine used to treat chronic hepatitis B).
- It is very important to tell your doctor if you are taking other medicines that may damage your kidneys.

These include:

- aminoglycosides, pentamidine or vancomycin (for bacterial infection)
- amphotericin B (for fungal infection)

- foscarnet, ganciclovir, or cidofovir (for viral infection)
- interleukin-2 (to treat cancer)
- adefovir dipivoxil (for *Hepatitis B Virus, HBV*)

- *Ricovir tablet* with other antiviral medicines that contain didanosine can raise the levels of didanosine in your blood and may reduce white blood cell (e.g. CD4 cells).

- Rarely, inflammation of the pancreas and lactic acidosis (excess lactic acid in the blood), which sometimes caused 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 *Ricovir tablet*

- How much to use

One tablet each day with food. Always take the dose recommended by your doctor. This is to make sure that your medicine is fully effective, and to reduce the risk of developing resistance to the treatment. Do not change the dose unless your doctor tells you to.

- Please refer to the patient information leaflets of the other antiretrovirals for guidance on how to take those medicines.

- When to use it

If you have problems with your kidneys, your doctor may advise you to take *Ricovir tablet* less frequently.

- How long to use it

Do not stop taking *Ricovir tablet* without your doctor's advice. Stopping treatment with *Ricovir tablet* may reduce the effectiveness of the treatment recommended by your doctor. Talk to your doctor before you stop taking *Ricovir tablet* for any reason, particularly if you are experiencing any side effects or you have another illness. Contact your doctor before you restart taking *Ricovir tablet*.

Tell your doctor immediately about new or unusual symptoms after you stop treatment, particularly symptoms

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you associate with hepatitis B infection.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- *If you forget to use it*

- It is important not to miss a dose of *Ricovir tablet*.
- If you miss a dose of *Ricovir tablet* when it is usually taken, take it as soon as you can, and then take your next dose at its regular time.
- If it is almost time 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 use too much (Overdose)*

If you accidentally take too many *Ricovir tablet* you may be at increased risk of experiencing possible side effects with this medicine (see Side effects).

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*

Look out for possible symptoms of lactic acidosis (excess of lactic acid in your blood) once you start taking *Ricovir tablet*.

Possible symptoms of lactic acidosis are:

- Deep, rapid breathing
- Drowsiness
- Nausea, vomiting and stomach pain

- This rare but serious side effect can cause enlargement of the liver and 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.

- In the treatment of HIV, combination antiretroviral therapies (including *Ricovir tablet*) may raise blood sugar, increase blood fats (hyperlipidemia),

cause changes to body fat, and resistance to insulin (see Side effects).

- 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 *Ricovir tablet* is started. These symptoms may indicate that your body's improved immune system in fighting infection.

Look out for symptoms of inflammation or infection soon after you start taking *Ricovir tablet*. If you notice symptoms of inflammation or infection, tell your doctor at once.

If you are diabetic, overweight or have high cholesterol, talk to your doctor. Tell your doctor before taking *Ricovir tablet* if you cannot tolerate lactose or if you have intolerance to any other sugars.

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

- *Things you must not do*

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

- *Ricovir tablet* does reduce the risk of passing on HIV to others through sexual contact or blood contamination. You must continue to take precautions to avoid this.

- *Things to be careful of*

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Try to avoid getting pregnant during treatment with *Ricovir tablet*. You need to use an effective method of contraception from becoming pregnant.

If you become pregnant, or plan to become pregnant, ask your doctor

about the potential benefits and risks of your antiretroviral therapy to you and your child.

You must not take *Ricovir tablet* during pregnancy unless had been discussed specifically with your doctor. Although there are limited clinical data on the use of *Ricovir tablet* in pregnant women, it is not usually used unless absolutely necessary.

Do not breast-feed during treatment with *Ricovir tablet*.

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

If you have taken *Ricovir tablet* 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 medicines like

Ricovir tablet (NRTIs) during pregnancy, the benefit from the protection against the virus outweighed the risk of side effects.

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

Ricovir tablet contains lactose

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Possible serious side effects: tell your doctor immediately

- Lactic acidosis (excess lactic acid in the blood) is a rare but serious side effect that can be fatal. The following side effects may be symptoms of lactic acidosis:
- Deep, rapid breathing
- Drowsiness
- Nausea, vomiting and stomach pain

Other possible serious side effects

The cause and the long-term effects of these changes are not yet known.

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The following side effects are very common (these can occur at least 10 in every 100 patients):

Diarrhoea, vomiting, nausea, dizziness.

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

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my [Consumers → Reporting → Reporting Side Effects to Medicines (ConSERF or Vaccines (AEFI))].

Storage and Disposal of RICOVIR tablet

- Storage

- Keep this medicine out of the sight and reach of children.
- Don't store this medicine above 30 °C.
- Store it in its original container.
- Do not use this medicine 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

- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product description

- What it looks like

Light blue colored, round biconvex film coated tablet debossed with "153" on one side and "M" on other side.

- Ingredients

- Active ingredient
Tenofovir Disoproxil Fumarate

- Inactive Ingredients

Purified water, Lactose monohydrate, Magnesium stearate, Microcrystalline cellulose, Croscarmellose sodium, film coat
{Lactose monohydrate, Hypromellose, Titanium dioxide, Triacetin /Glycerol triacetate, FD & C Blue #2}.

- MAL number:

MAL11030098ARZ

Manufacturer

Mylan Laboratories Limited
F-4 & F- 12, MIDC, Malegaon,
Sinnar, Nashik - 422 113,
Maharashtra, India

Product Registration Holder

Mylan Healthcare Sdn Bhd
15-03 & 15-04, Level 15, Imazium,
No. 8, Jalan SS 21/37,
Damansara Uptown, 47400,
Petaling Jaya, Selangor,
Malaysia.

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