

TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 Tablets

300 mg tenofovir disoproxil maleate/200 mg emtricitabine

CONSUMER MEDICINE INFORMATION

What is in this leaflet

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

This leaflet answers some common questions about TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist about your medical condition or treatment. If you have further questions, please ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 is used for

TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 is used to treat Human Immunodeficiency Virus (HIV) infection in adults. This medicine must be taken in combination with other anti-HIV medicines.

TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 consists of two medicines:

- tenofovir disoproxil maleate
- emtricitabine

These are combined in one tablet to help control Human Immunodeficiency Virus (HIV) infection.

TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 contains two active ingredients that belong to a group of antiviral medicines known as nucleoside and nucleotide reverse transcriptase inhibitors (NRTI).

TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 is used:

- to treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults when taken in combination with other anti-HIV medicines;
- to help reduce the risk of getting HIV infection when used with safer sex practices in:

HIV-negative men who have sex with men, who are at high risk of getting infected with HIV-1 through sex.

Male-female sex partners when one partner has HIV-1 infection and the other does not.

When TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 is used to treat HIV infection

When used with other HIV-1 medicines to treat HIV-1 infection, TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 may help:

- Reduce the amount of HIV-1 in your blood. This is called “viral load”.
- Increase the number of CD4+ (T) cells in your blood that help fight off other infections.

Reducing the amount of HIV-1 and increasing the CD4+ (T) cells in your blood may help improve your immune system.

This may reduce your risk of death or infections that can happen when your immune system is weak.

Use in Children and Elderly

TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 is for adults.

Do not take TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 if you are under the age of 18 years.

Do not take TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 if you are over

the age of 65 before discussing with your doctor.

Does TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 cure HIV OR AIDS?

TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 is not a cure for HIV infection or AIDS. While taking TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 you may still develop infections or other illnesses associated with HIV infection.

If you have HIV-1 infections, you must keep taking HIV-1 medicines to control HIV-1 infection and decrease HIV-related illnesses.

Does TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 reduce the risk of HIV to others?

TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 does not reduce the risk of passing HIV to others through sexual contact or blood contamination.

It is important to continue to take appropriate precautions to prevent passing HIV to others.

When TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 is used to reduce the risk of HIV infection

When used with safer sex practices, TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 may help to reduce the risk of getting HIV-1 infection if you are at high risk of getting HIV infection.

TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 reduces the risk of getting HIV-1 when you have been taking it before you are exposed to HIV-1.

Before you take TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200

Who must not take it

Together with your doctor, you need to decide whether TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 is right for you.

Do not take TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 if you are allergic to:

- tenofovir,
- tenofovir disoproxil maleate,
- tenofovir disoproxil fumarate,
- any of the other ingredients of TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- rash, itching or hives on the skin
- swelling of the face, lips, tongue or other parts of the body

The ingredients of TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 are listed in the product description section of this leaflet.

Do not take TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 if you are already taking any of the components of TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 (tenofovir disoproxil maleate or emtricitabine).

Do not take TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 if you are taking lamivudine.

Do not take TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 if you are taking adefovir dipivoxil.

Do not take TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 if you are taking tenofovir alafenamide.

Do not take TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 after the expiry or "use by" date (EXP) printed on the packaging.

If you take it after the expiry date has passed, it may not work as well.

Do not take TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be taking TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200, talk to your doctor.

For people using TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 to reduce the risk of getting HIV-1 infection:

TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 can only help reduce your risk of getting HIV-1 before you are infected.

Do not take TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 to help reduce your risk of getting HIV-1 if:

- you already have HIV-1 infection. If you are HIV-positive, you need to take other medicines with TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 to treat HIV. TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN

300/200 by itself is not a complete treatment for HIV.

- you do not know your HIV-1 infection status. You may already be HIV-positive. You need to take other HIV-1 medicines with TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 to treat HIV-1.
- Many HIV-1 tests can miss HIV-1 infection in a person who has recently become infected. If you have flu-like symptoms, you could have recently become infected with HIV-1. Tell your healthcare provider if you had a flu-like illness within the last month before starting TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 or at any time while taking TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200. Symptoms of new HIV-1 infection include: tiredness, fever, joint or muscle aches, headache, sore throat, vomiting or diarrhoea, rash, night sweats or enlarged lymph nodes in the neck or groin.

Before you start to take it:

Tell your doctor if you are allergic to foods, dyes, preservatives or any other medicines.

Tell your doctor if you are pregnant, trying to become pregnant or breast feeding.

The safe use of TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 in pregnancy has not been demonstrated. For this reason, it is important that women of child-bearing age receiving treatment with TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 use an effective method of contraception to avoid becoming pregnant.

If you are a female who is taking TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 to reduce the risk of getting HIV-1 infection and you become

pregnant while taking TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200, talk to your healthcare provider to decide if you should keep taking TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200.

The active substances in this medicine (tenofovir disoproxil maleate and emtricitabine) have been found in breast milk at low concentrations.

Consequently, it is recommended that nursing mothers do not breast-feed during treatment with TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200. In general, women infected with HIV should not breast-feed their infants in order to avoid transmission of HIV to their newborn infant.

Tell your doctor if you have liver problems, including hepatitis B, or C virus infection.

Tell your doctor if you are taking medication to treat your hepatitis C virus (HCV) infection (e.g. ledipasvir/sofosbuvir, sofosbuvir/velpatasvir).

Tell your doctor if you have kidney problems.

Tell your doctor if you have or have ever had abnormal bones or bone difficulties.

This medicine is only available from a pharmacist after it has been prescribed by a doctor who specialises in the treatment of HIV infection.

If you wish to continue receiving treatment with TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 it is important you remain under the care of a hospital or doctor who specialises in the treatment of HIV infection.

Avoid doing things that increase your risk of getting HIV-1 or spreading HIV-1 to other people:

- Do not have any kind of sex without protection. Always practice safer sex. Use latex or

non-latex condoms, except lambskin, to reduce contact with semen, vaginal fluids, or blood.

- Do not share personal items that can have blood or body fluids on them, such as toothbrushes and razor blades.
- Do not share or re-use needles or other injection equipment.

Ask your healthcare provider if you have any questions about how to prevent getting HIV-1 or spreading HIV-1 to other people.

If you have a long standing viral infection of your liver (hepatitis B) it may flare up when you stop taking TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200.

This can cause serious illness particularly if your liver is already not working very well. If you have both HIV and hepatitis B, when you start taking TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 and even after you stop, your doctor is likely to arrange tests from time to time to check how well your liver is working.

Taking other medicines

If you have HIV infections your doctor will generally prescribe TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 in combination with other anti-HIV medicines.

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Tell your doctor if are taking:

- didanosine (also known as ddI or Videx).
- ledipasvir with sofosbuvir (HARVONI®)
- sofosbuvir/velpatasvir (EPCLUSA®)
- sofosbuvir/velpatasvir/voxilaprevir (e.g. VOSEVI®)

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 tablets with other medicines.

How to take TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200

Take TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 exactly as prescribed. The usual dose is one TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 tablet once daily.

Take TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 at the same time each day to keep TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 blood levels constant.

TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 is best taken with a meal or just afterwards, however taking it without food should not reduce the effectiveness of the medicine.

TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 is absorbed rapidly. Do not take another TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 dose if vomiting has occurred unless it occurs within 1 hour after taking TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200.

How to take it

Take one TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 tablet once daily or as advised by your doctor.

If you are not sure how much TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN

300/200 you should take, check with your doctor or pharmacist. Do not change the amount of TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 you take unless told to do so by your doctor.

Your doctor will tell you how much TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 to take and how often to take it. You will also find this information on the label of your medicine container.

Because your medicine helps to control your condition, but does not cure it, you will need to take TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 every day. If you are taking TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 to reduce the risk of HIV-1 infection, take TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 every day for the period of time as prescribed by your doctor.

Do not miss any doses of TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200. Missing a dose lowers the amount of medicine in your blood.

Do not stop taking TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 without first talking to your doctor.

If you forget to take TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200

It is important to take the prescribed daily dose in order to get the maximum benefit of treatment.

If you forget to take your daily dose of TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 take it as soon as you remember that day and then go back to taking your medicine as you would normally.

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

Do not take more than one TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 tablet in a day.

If you take too much (overdose)?

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or in New Zealand the Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to the accident and emergency department at your nearest hospital if you think you or anyone else may have taken too many TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 tablets. Do this even if there are no signs of discomfort or poisoning. This may need urgent medical attention.

While you are taking TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200

Things you must do

Tell your doctor or pharmacist that you are taking TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 if you are about to be started on any other medicines.

Tell your doctor if you become pregnant or are trying to become pregnant.

Tell your doctor if for any reason you have not taken your medicine exactly as prescribed.

**If you are taking
TENOFVIR DISOPROXIL
EMTRICITABINE MYLAN
300/200 to reduce your risk
of getting HIV**

**Just taking TENOFVIR
DISOPROXIL EMTRICITABINE
MYLAN 300/200 may not keep you
from getting HIV.**

**You must continue using safer sex
practices while you are taking
TENOFVIR DISOPROXIL
EMTRICITABINE MYLAN
300/200 to reduce your risk of
getting HIV.**

**You must stay HIV-negative to
keep taking TENOFVIR
DISOPROXIL EMTRICITABINE
MYLAN 300/200 to reduce your
risk of infection.**

Know your HIV status and the HIV
status of your partners.

Get tested for HIV at least every 3
months or when your healthcare
provider tells you.

Get tested for other sexually
transmitted infections such as
syphilis and gonorrhoea. These
infections make it easier for HIV to
infect you. TENOFVIR
DISOPROXIL EMTRICITABINE
MYLAN 300/200 will not stop you
from getting these other infections.

If you think you were exposed to
HIV, tell your healthcare provider
right away. They may want to do
more tests to be sure you are still
HIV-negative.

Get information and support to help
reduce risky sexual behaviour.

Have fewer sex partners.

**Do not miss any doses of
TENOFVIR DISOPROXIL
EMTRICITABINE MYLAN
300/200. Missing doses may
increase your risk of getting HIV
infection.**

If you do become HIV-positive, you
need more medicine than
TENOFVIR DISOPROXIL
EMTRICITABINE MYLAN
300/200 alone to treat HIV.
TENOFVIR DISOPROXIL

EMTRICITABINE MYLAN
300/200 by itself is not a complete
treatment for HIV.

If you have HIV and take only
TENOFVIR DISOPROXIL
EMTRICITABINE MYLAN
300/200, over time your HIV may
become harder to treat.

Things you must not do

**Do not stop taking TENOFVIR
DISOPROXIL EMTRICITABINE
MYLAN 300/200 or change the
dose without first checking with
your doctor.**

**Do not give this medicine to anyone
else even if their symptoms seem
similar to yours.**

**Do not use TENOFVIR
DISOPROXIL EMTRICITABINE
MYLAN 300/200 to treat any other
complaints unless your doctor says
to.**

Things to be careful of

**Be careful driving or operating
machinery until you know how
TENOFVIR DISOPROXIL
EMTRICITABINE MYLAN
300/200 affects you.**

SIDE EFFECTS

Like all medicines, TENOFVIR
DISOPROXIL EMTRICITABINE
MYLAN 300/200 can have side
effects, although not everybody gets
them. Some may be serious and need
medical attention.

**Check with your doctor as soon as
possible if you have any problems
while taking TENOFVIR
DISOPROXIL EMTRICITABINE
MYLAN 300/200, even if you do
not think the problems are
connected with the medicine or are
not listed in this leaflet.**

**Tell your doctor or pharmacist if
you notice any of the following and
they worry you:**

- Diarrhoea
- Nausea

- tiredness
- Headache
- Vomiting
- Dizziness
- Depression
- Problems sleeping
- Abnormal dreams
- Rash

Common side effects in people who
take TENOFVIR DISOPROXIL
EMTRICITABINE MYLAN
300/200 to reduce the risk of getting
HIV-1 infection include:

- stomach-area (abdomen) pain
- headache
- decreased weight

Ask your doctor or pharmacist to
answer any question you may have
about these or other effects.

Allergy

Some people are allergic to
medicines.

**If you have any of the following
symptoms soon after taking your
medicine, DO NOT TAKE ANY
MORE TENOFVIR
DISOPROXIL EMTRICITABINE
MYLAN 300/200 and tell your
doctor IMMEDIATELY or go to
the accident and emergency
department at your nearest
hospital.**

- Skin troubles such as lumpy skin
rash or “hives”
- Swelling of the face, lips, mouth
or throat which may cause
difficulty in swallowing or
breathing
- Wheezing, chest pain or tightness
- Fainting

**These are very serious effects. If
you have them, you may have a
serious allergic reaction. You may
need urgent medical attention or
hospitalisation. All of these side
effects are very rare.**

Pancreatitis

If you have any of the following symptoms after starting your medication, tell your doctor IMMEDIATELY or go to the accident and emergency department at your nearest hospital.

- Severe stomach pain or cramps
- Nausea
- Vomiting

These side effects may be due to a condition called pancreatitis which sometimes occurs in patients taking anti-HIV medicines.

Serious Liver Problems (hepatotoxicity)

If you have any of the following symptoms while taking your medication, tell your doctor IMMEDIATELY or go to the accident and emergency department at your nearest hospital.

- Your skin or the white part of your eyes turns yellow (jaundice)
- Your urine turns dark
- Your bowel movements (stools) turn light in colour
- You don't feel like eating food for several days or longer
- Nausea
- Stomach pains

These side effects may be due to a condition called hepatotoxicity with liver enlargement and fat deposits in the liver (steatosis) which sometimes occurs in patients taking anti-HIV medicines.

Lactic Acidosis

If you have any of the following symptoms after taking your medication, tell your doctor IMMEDIATELY or go to the accident and emergency department at your nearest hospital:

- You feel very weak or tired

- You have unusual (not normal) muscle pain
- You have trouble breathing
- You have stomach pain with nausea and vomiting
- You feel cold, especially in your arms and legs
- You feel dizzy or light headed
- You have a fast or irregular heartbeat

These side effects may be due to a condition called lactic acidosis (build-up of an acid in the blood).

Lactic acidosis can be a medical emergency and may need to be treated in the hospital.

You may be more likely to get lactic acidosis or liver problems if you are female, very overweight (obese), or have been taking similar nucleoside analog-containing medicines, like TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200, for a long time.

Hepatic Flares

Your doctor should test you to see if you have chronic hepatitis B infection before you start taking TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200.

If you have chronic hepatitis B infection you should not stop your TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 treatment without first discussing this with your doctor, as some patients have had blood tests or symptoms indicating a worsening of their hepatitis ("hepatic flare") after stopping individual components (tenofovir disoproxil maleate and emtricitabine) of TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200.

You may require medical exams and blood tests for several months after stopping treatment.

TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 is not approved for the

treatment of hepatitis B, so you must discuss your hepatitis B therapy with your healthcare provider.

Other possible side effects:

This list of side effects is not complete.

TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 may cause other serious side effects. Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list:

New and worse kidney problems

If you have had kidney problems in the past or need to take another drug that can cause kidney problems, your healthcare provider may need to perform additional blood tests to check your kidneys.

Bone problems

Bone problems can happen in some people who take TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200. Bone problems include bone pain, or softening or thinning of bones, which may lead to fractures. Your healthcare provider may need to do tests to check your bones.

Signs and symptoms of inflammation

In some patients with advanced HIV infection (AIDS), 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 an improvement in the body's immune response, which lets the body fight infections that may have been present with no obvious symptoms. If you notice any symptoms of infection, please tell your doctor immediately.

Some people may get other side effects while taking TENOFOVIR DISOPROXIL EMTRICITABINE MYLAN 300/200. If you are concerned, talk to your doctor or pharmacist.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side-effects. Most of them are very rare and you may not experience any of them.

After taking TENOFVIR DISOPROXIL EMTRICITABINE MYLAN 300/200

Storage

Keep TENOFVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 tablets where children cannot reach them.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store them.

Keep TENOFVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 tablets in a cool, dry place where it stays below 25°C.

Do not store TENOFVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 tablets or any other medicine in a bathroom or near a sink.

Do not leave TENOFVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 tablets in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep your TENOFVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 tablets in the bottle with the cap tightly closed until you take them.

If you take TENOFVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 tablets out of their pack they may not keep well.

Disposal

If your doctor tells you to stop taking TENOFVIR DISOPROXIL EMTRICITABINE MYLAN 300/200, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What it looks like

TENOFVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 tablets are a light green, film coated, capsule shaped, biconvex tablet debossed with 'M' on one side of the tablet and 'ETM' on the other side.

Ingredients

Each TENOFVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 tablet contains the following active ingredients:

- 300 mg tenofovir disoproxil maleate
- 200 mg emtricitabine

Each TENOFVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 tablet contains the following inactive ingredients

- microcrystalline cellulose
- hypromellose
- iron oxide red
- colloidal anhydrous silica
- lactose monohydrate
- magnesium stearate
- Opadry II complete film coating system 32K510087 GREEN (ARTG 114524)

Sponsor

TENOFVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 is supplied in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond
30 – 34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au
Phone: 1800 274 276

TENOFVIR DISOPROXIL EMTRICITABINE MYLAN 300/200 is supplied in New Zealand by:

Viatris Ltd

PO Box 11-183

Ellerslie

AUCKLAND

www.viatris.co.nz

Telephone: 0800 168 169

Australian registration numbers:

**TENOFVIR DISOPROXIL
EMTRICITABINE MYLAN
300/200 film coated tablet bottle:**

AUST R 265834

This leaflet was prepared in July 2021.

**Tenofovir Disoproxil Emtricitabine
Mylan 300/200_cmi\Jul21/00**