

# TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

### 1. Why am I taking TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200?

TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 contains the active ingredients tenofovir disoproxil maleate and emtricitabine. It is used to treat Human Immunodeficiency Virus (HIV) infection in adults. For more information, see Section [1. Why am I taking TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200?](#) in the full CMI.

### 2. What should I know before I take TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200?

Do not take if you have ever had an allergic reaction to tenofovir disoproxil maleate/emtricitabine or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I take TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I take TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200?

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

More instructions can be found in Section [4. How do I take TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200?](#) in the full CMI.

### 5. What should I know while taking TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200?

|                                    |                                                                                                                                                                                                                                                                                                                            |
|------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Things you should do</b>        | <ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are taking this medicine.</li><li>Tell your doctor if you become pregnant or are trying to become pregnant.</li><li>Tell your doctor if for any reason you have not taken your medicine exactly as prescribed.</li></ul> |
| <b>Things you should not do</b>    | <ul style="list-style-type: none"><li>Do not stop taking this medicine or change the dose without first checking with your doctor.</li><li>Do not give this medicine to anyone else even if their symptoms seem similar to yours.</li></ul>                                                                                |
| <b>Driving or using machines</b>   | <ul style="list-style-type: none"><li>Be careful before you drive or use any machines or tools until you know how TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 affects you.</li></ul>                                                                                                                                |
| <b>Looking after your medicine</b> | <ul style="list-style-type: none"><li>Keep tablets below 25°C.</li><li>Keep your tablets in the bottle with the cap tightly closed until you take them.</li></ul>                                                                                                                                                          |

For more information, see Section [5. What should I know while taking TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200?](#) in the full CMI.

### 6. Are there any side effects?

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

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200

Active ingredient(s): *tenofovir disoproxil maleate and emtricitabine*

## Consumer Medicine Information (CMI)

This leaflet provides important information about taking TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200.**

**Where to find information in this leaflet:**

- [1. Why am I taking TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200?](#)
- [2. What should I know before I take TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200?](#)
- [5. What should I know while taking TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200?

TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 contains the active ingredients **tenofovir disoproxil maleate and emtricitabine**. These are combined in one tablet to help control Human Immunodeficiency Virus (HIV) infection.

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

When used with other HIV-1 medicines to treat HIV-1 infection, TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 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.

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

TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 is not a cure for HIV infection or AIDS. While taking TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 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 VIATRIS 300/200 reduce the risk of HIV to others?

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

When used with safer sex practices, TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 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 VIATRIS 300/200 reduces the risk of getting HIV-1 when you have been taking it before you are exposed to HIV-1.

## 2. What should I know before I take TENOFIVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200?

### Warnings

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

#### Do not take TENOFIVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 if:

- you are allergic to:
  - tenofovir
  - tenofovir disoproxil maleate
  - tenofovir disoproxil fumarate
  - or any of the ingredients listed at the end of this leaflet
  - 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

Always check the ingredients to make sure you can take this medicine.

- you are already taking any of the components of TENOFIVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 (tenofovir disoproxil maleate or emtricitabine)
- you are taking lamivudine
- you are taking adefovir dipivoxil
- you are taking tenofovir alafenamide
- the expiry or "use by" date (EXP) printed on the packaging has passed. If you take it after the expiry date has passed, it may not work as well.
- the packaging is torn or shows signs of tampering

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

#### Do not take TENOFIVIR DISOPROXIL EMTRICITABINE VIATRIS 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 TENOFIVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 to treat HIV. TENOFIVIR DISOPROXIL EMTRICITABINE VIATRIS 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 TENOFIVIR DISOPROXIL EMTRICITABINE VIATRIS 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 TENOFIVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 or at any time while taking TENOFIVIR DISOPROXIL EMTRICITABINE VIATRIS 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.

#### Check with your doctor if you:

- are allergic to foods, dyes, preservatives or any other medicines
- have or have had any of the following medical conditions:
  - 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
  - kidney problems
  - abnormal bones or bone difficulties
- take any medicines for any other condition

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 TENOFIVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 it is important you remain under the care of a hospital or doctor who specialises in the treatment of HIV infection.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### 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 TENOFIVIR DISOPROXIL EMTRICITABINE VIATRIS 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 VIATRIS 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.

### **Pregnancy and breastfeeding**

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

**The safe use of TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 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 VIATRIS 300/200 use an effective method of contraception to avoid becoming pregnant.**

If you are a female who is taking TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 to reduce the risk of getting HIV-1 infection and you become pregnant while taking TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200, talk to your healthcare provider to decide if you should keep taking TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 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 breastfeed during treatment with TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 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.

### **Use in children**

TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 is for adults.

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

### **Use in elderly**

**Do not take TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 if you are over the age of 65 before discussing with your doctor.**

## **3. What if I am taking other medicines?**

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

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

**Some medicines may interfere with TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 and affect how it works. These include:**

- didanosine

- ledipasvir with sofosbuvir
- sofosbuvir/velpatasvir
- sofosbuvir/velpatasvir/voxilaprevir

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 VIATRIS 300/200 tablets with other medicines.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200.**

## **4. How do I take TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200?**

### **How much to take**

- Take TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 exactly as prescribed. The usual dose is one TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 tablet once daily.
- TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 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 VIATRIS 300/200 is absorbed rapidly. Do not take another TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 dose if vomiting has occurred unless it occurs within 1 hour after taking TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200.

### **When to take TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200**

- TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 should be taken at the same time each day to keep the tenofovir and emtricitabine blood levels constant.

### **How to take TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200**

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

If you are not sure how much TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 you should take, check with your doctor or pharmacist. Do not change the amount of TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 you take unless told to do so by your doctor. Your doctor will tell you how much TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 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 VIATRIS 300/200 every day. If you are taking TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 to reduce the risk of HIV-1 infection, take TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200

every day for the period of time as prescribed by your doctor.

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

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

### **If you forget to take TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 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 VIATRIS 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 the dose you missed.**

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

### **If you take too much TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200**

If you think that you or anyone else has taken too much TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200, urgent medical attention may be needed.

**You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while taking TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200?**

### **Things you should do**

Tell your doctor or pharmacist that you are taking TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 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 TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 to reduce your risk of getting HIV**

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

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

**You must stay HIV-negative to keep taking TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 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. TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 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 TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200. Missing doses may increase your risk of getting HIV infection.**

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

TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 by itself is not a complete treatment for HIV.

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

### **Call your doctor straight away if you:**

- Become pregnant or are trying to become pregnant.
- For any reason you have not taken your medicine exactly as prescribed.
- Think you were exposed to HIV. Your doctor may want to do more tests to be sure you are still HIV-negative.

Remind any doctor, dentist or pharmacist you visit that you are taking TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200.

### **Things you should not do**

- Do not stop taking TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 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 TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 to treat any other complaints unless your doctor says to.

### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 affects you.**

## Looking after your medicine

- Keep TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 tablets below 25°C.
- Keep your TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 tablets in the bottle with the cap tightly closed until you take them.

If you take tablets out of their pack they may not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

### Keep it where young children cannot reach it.

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

## Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

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.

### Less serious side effects

| Less serious side effects                                                                                                                                                                                                                            | What to do                                                                      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| <ul style="list-style-type: none"><li>• diarrhoea</li><li>• nausea</li><li>• tiredness</li><li>• headache</li><li>• vomiting</li><li>• dizziness</li><li>• depression</li><li>• problems sleeping</li><li>• abnormal dreams</li><li>• rash</li></ul> | <b>Speak to your doctor if you have any of these less serious side effects.</b> |
| <b>TENOFOVIR DISOPROXIL<br/>EMTRICITABINE VIATRIS 300/200 to</b>                                                                                                                                                                                     |                                                                                 |

| Less serious side effects                                                                                                                                                              | What to do |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| <b>reduce the risk of getting HIV-1 infection include:</b> <ul style="list-style-type: none"><li>• stomach-area (abdomen) pain</li><li>• headache</li><li>• decreased weight</li></ul> |            |

### Serious side effects

| Serious side effects                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | What to do                                                                                                                                                  |
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| <b>Allergy:</b> <ul style="list-style-type: none"><li>• skin troubles such as lumpy skin rash or "hives"</li><li>• swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing</li><li>• wheezing, chest pain or tightness</li><li>• fainting</li></ul> <b>Pancreatitis:</b> <ul style="list-style-type: none"><li>• severe stomach pain or cramps</li><li>• nausea</li><li>• vomiting</li></ul> <b>Serious Liver Problems (hepatotoxicity):</b> <ul style="list-style-type: none"><li>• Your skin or the white part of your eyes turns yellow (jaundice)</li><li>• Your urine turns dark</li><li>• Your bowel movements (stools) turn light in colour</li><li>• You don't feel like eating food for several days or longer</li><li>• Nausea</li><li>• Stomach pains</li></ul> <p>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.</p> <b>Lactic Acidosis:</b> <ul style="list-style-type: none"><li>• You feel very weak or tired</li><li>• You have unusual (not normal) muscle pain</li><li>• You have trouble breathing</li><li>• You have stomach pain with nausea and vomiting</li><li>• You feel cold, especially in your arms and legs</li><li>• You feel dizzy or light-headed</li><li>• You have a fast or irregular heartbeat</li></ul> <p>These side effects may be due to a condition called lactic acidosis (build-</p> | <b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b> |

| Serious side effects                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | What to do |
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| <p>up of an acid in the blood). Lactic acidosis can be a medical emergency and may need to be treated in the hospital.</p> <p>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 VIATRIS 300/200, for a long time.</p> <p><b>Hepatic Flares:</b></p> <ul style="list-style-type: none"> <li>Your doctor should test you to see if you have chronic hepatitis B infection before you start taking TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200. If you have chronic hepatitis B infection you should not stop your TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 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 VIATRIS 300/200. You may require medical exams and blood tests for several months after stopping treatment. TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 is not approved for the treatment of hepatitis B, so you must discuss your hepatitis B therapy with your healthcare provider.</li> </ul> <p><b>New and worse kidney problems:</b></p> <ul style="list-style-type: none"> <li>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.</li> </ul> <p><b>Bone problems:</b></p> <ul style="list-style-type: none"> <li>Bone problems can happen in some people who take TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS</li> </ul> |            |

| Serious side effects                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | What to do |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| <p>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.</p> <p><b>Signs and symptoms of inflammation:</b></p> <ul style="list-style-type: none"> <li>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.</li> </ul> |            |

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 contains

|                                                 |                                                                                                                                                                                                                         |
|-------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Active ingredient (main ingredient)</b>      | <ul style="list-style-type: none"> <li>300 mg tenofovir disoproxil maleate</li> <li>200 mg emtricitabine</li> </ul>                                                                                                     |
| <b>Other ingredients (inactive ingredients)</b> | <ul style="list-style-type: none"> <li>microcrystalline cellulose</li> <li>hypromellose</li> <li>iron oxide red</li> <li>colloidal anhydrous silica</li> <li>lactose monohydrate</li> <li>magnesium stearate</li> </ul> |



|                            |                                                                                                                       |
|----------------------------|-----------------------------------------------------------------------------------------------------------------------|
|                            | <ul style="list-style-type: none"> <li>Opadry II complete film coating system 32K510087 GREEN (ID: 114524)</li> </ul> |
| <b>Potential allergens</b> | lactose                                                                                                               |

**Do not take this medicine if you are allergic to any of these ingredients.**

### **What TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200 looks like**

TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200

tablets are light green, filmcoated, capsule shaped, biconvex tablets debossed with 'M' on one side of the tablet and 'ETM' on the other side (AUST R 265834).

### **Who distributes TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200**

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

This leaflet was prepared in December 2025.

**TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS  
300/200\_cmi\Dec25/00**