

# CIPLA TENOFOVIR + EMTRICITABINE 300/200

## Tablets

300 mg tenofovir disoproxil fumarate / 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 of the common questions about CIPLA TENOFOVIR + EMTRICITABINE 300/200. It does not contain all of 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 your pharmacist.

Keep this leaflet with your CIPLA TENOFOVIR + EMTRICITABINE 300/200 medicine. You may need to read it again.

#### What CIPLA TENOFOVIR + EMTRICITABINE 300/200 is used for

##### What is it used for

- 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.

##### How CIPLA TENOFOVIR + EMTRICITABINE 300/200 works

CIPLA TENOFOVIR + EMTRICITABINE 300/200 consists of two medicines combined in one tablet:

- tenofovir disoproxil fumarate, also called tenofovir DF
- emtricitabine or FTC

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

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

##### When CIPLA TENOFOVIR + EMTRICITABINE 300/200 is used to treat HIV infection

When used with other HIV-1 medicines to treat HIV-1 infection, CIPLA TENOFOVIR + EMTRICITABINE 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

CIPLA TENOFOVIR + EMTRICITABINE 300/200 is for adults.

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

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

#### Does CIPLA TENOFOVIR + EMTRICITABINE 300/200 cure HIV OR AIDS

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

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

#### Does CIPLA TENOFOVIR + EMTRICITABINE 300/200 reduce the risk of passing HIV to others

CIPLA TENOFOVIR + EMTRICITABINE 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 CIPLA TENOFOVIR + EMTRICITABINE 300/200 is used to reduce the risk of HIV infection

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

CIPLA TENOFOVIR + EMTRICITABINE 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 CIPLA TENOFOVIR + EMTRICITABINE 300/200

##### When you must not take it

**Together with your doctor, you need to decide whether CIPLA TENOFOVIR + EMTRICITABINE 300/200 is right for you.**

**Do not take CIPLA TENOFOVIR + EMTRICITABINE 300/200 if you are allergic to:**

- tenofovir
- tenofovir DF
- any of the other ingredients of CIPLA TENOFOVIR + EMTRICITABINE 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 CIPLA TENOFOVIR + EMTRICITABINE 300/200 are listed in the product description section of this leaflet.**

**Do not take CIPLA TENOFOVIR + EMTRICITABINE 300/200 if you are already taking any of the components of CIPLA TENOFOVIR + EMTRICITABINE 300/200 (tenofovir DF or emtricitabine).**

**Do not take CIPLA TENOFOVIR + EMTRICITABINE 300/200 if you are taking lamivudine.**

**Do not take CIPLA TENOFOVIR + EMTRICITABINE 300/200 if you are taking adefovir dipivoxil.**

**Do not take CIPLA TENOFOVIR + EMTRICITABINE 300/200 if you are taking tenofovir alafenamide.**

**Do not take CIPLA TENOFOVIR + EMTRICITABINE 300/200 after the expiry or "use by" date (EXP) printed on the bottle.**

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

**Do not take CIPLA TENOFOVIR + EMTRICITABINE 300/200 if the packaging is torn or shows signs of tampering.**

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

*For people using CIPLA TENOFOVIR + EMTRICITABINE 300/200 to reduce the risk of getting HIV-1 infection:*

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

**Do not take CIPLA TENOFOVIR + EMTRICITABINE 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 CIPLA TENOFOVIR + EMTRICITABINE 300/200 to treat HIV. CIPLA TENOFOVIR + EMTRICITABINE 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 CIPLA TENOFOVIR + EMTRICITABINE 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 CIPLA TENOFOVIR + EMTRICITABINE 300/200 or at any time while taking CIPLA TENOFOVIR + EMTRICITABINE 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 CIPLA TENOFOVIR + EMTRICITABINE 300/200 in pregnancy has not been demonstrated. For this reason, it is important that women of child-bearing age receiving treatment with CIPLA TENOFOVIR + EMTRICITABINE 300/200 use an effective method of contraception to avoid becoming pregnant.**

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

The active substances in this medicine (tenofovir disoproxil fumarate 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 CIPLA TENOFOVIR + EMTRICITABINE 300/200. In general, women infected with HIV should not breastfeed 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 CIPLA TENOFOVIR + EMTRICITABINE 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 CIPLA TENOFOVIR + EMTRICITABINE 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 CIPLA TENOFOVIR + EMTRICITABINE 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.

**CIPLA TENOFOVIR + EMTRICITABINE 300/200 contains Lactose Monohydrate**

This medicine also contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars (e.g. lactose), talk to your doctor before taking this medicine.

#### *Taking other medicines*

**If you have HIV infection your doctor will generally prescribe CIPLA TENOFOVIR + EMTRICITABINE 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).
- ledipasvir/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 CIPLA TENOFOVIR + EMTRICITABINE 300/200 tablets with other medicines.

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#### **How to take CIPLA TENOFOVIR + EMTRICITABINE 300/200**

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Take CIPLA TENOFOVIR + EMTRICITABINE 300/200 exactly as prescribed. The usual dose is one CIPLA TENOFOVIR + EMTRICITABINE 300/200 tablet orally once daily. Take CIPLA TENOFOVIR + EMTRICITABINE 300/200 at the same time each day to keep CIPLA TENOFOVIR + EMTRICITABINE 300/200 blood levels constant.

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

#### *How much to take*

**Take one CIPLA TENOFOVIR + EMTRICITABINE 300/200 tablet once daily or as advised by your doctor.**

If you are not sure how much CIPLA TENOFOVIR + EMTRICITABINE 300/200 you should take, check with your doctor or

pharmacist. Do not change the amount of CIPLA TENOFOVIR + EMTRICITABINE 300/200 you take unless told to do so by your doctor.

Your doctor will tell you how much CIPLA TENOFOVIR + EMTRICITABINE 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 CIPLA TENOFOVIR + EMTRICITABINE 300/200 every day. If you are taking CIPLA TENOFOVIR + EMTRICITABINE 300/200 to reduce the risk of HIV-1 infection, take CIPLA TENOFOVIR + EMTRICITABINE 300/200 every day for the period of time as prescribed by your doctor.**

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

**Do not stop taking CIPLA TENOFOVIR + EMTRICITABINE 300/200 without first talking to your doctor.**

#### *When to take it*

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

#### *If you forget to take CIPLA TENOFOVIR + EMTRICITABINE 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 CIPLA TENOFOVIR + EMTRICITABINE 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 CIPLA TENOFOVIR + EMTRICITABINE 300/200 tablet in a day.**

#### *If you take too much (overdose)*

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

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#### **While you are taking CIPLA TENOFOVIR + EMTRICITABINE 300/200**

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#### *Things you must do*

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

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

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

**You must stay HIV-negative to keep taking CIPLA TENOFOVIR + EMTRICITABINE 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 gonorrhea. These infections make it easier for HIV to infect you. CIPLA TENOFOVIR + EMTRICITABINE 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 CIPLA TENOFOVIR + EMTRICITABINE 300/200. Missing doses may increase your risk of getting HIV infection.**

If you do become HIV-positive, you need more medicine than CIPLA TENOFOVIR + EMTRICITABINE 300/200 alone to treat HIV. CIPLA TENOFOVIR + EMTRICITABINE 300/200 by itself is not a complete treatment for HIV.

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

*Things you must not do*

**Do not stop taking CIPLA TENOFOVIR + EMTRICITABINE 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 CIPLA TENOFOVIR + EMTRICITABINE 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 CIPLA TENOFOVIR + EMTRICITABINE 300/200 affects you.**

## SIDE EFFECTS

Like all medicines, CIPLA TENOFOVIR + EMTRICITABINE 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 CIPLA TENOFOVIR + EMTRICITABINE 300/200, even if you do not think the problems are connected**

**with the medicine or are not listed in this leaflet.**

The most common side effects in people taking tenofovir disoproxil fumarate/emtricitabine to treat HIV-1 infection include:

- diarrhoea
- nausea
- tiredness
- headache
- dizziness
- depression
- problems sleeping
- abnormal dreams
- rash

Common side effects in people who take tenofovir disoproxil fumarate/emtricitabine 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 CIPLA TENOFOVIR + EMTRICITABINE 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-area 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 CIPLA TENOFOVIR + EMTRICITABINE 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 CIPLA TENOFOVIR + EMTRICITABINE 300/200.**

**If you have chronic hepatitis B infection you should not stop your CIPLA TENOFOVIR + EMTRICITABINE 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 fumarate and emtricitabine) of CIPLA TENOFOVIR + EMTRICITABINE 300/200.**

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

CIPLA TENOFOVIR + EMTRICITABINE 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.

CIPLA TENOFOVIR + EMTRICITABINE 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 fumarate/emtricitabine. 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 CIPLA TENOFOVIR + EMTRICITABINE 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.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly at <http://www.tga.gov.au/reporting-problems>. By reporting side effects you can help provide more information on the safety of this medicine.

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#### **After taking CIPLA TENOFOVIR + EMTRICITABINE 300/200**

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##### **Storage**

**Keep CIPLA TENOFOVIR + EMTRICITABINE 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 CIPLA TENOFOVIR + EMTRICITABINE 300/200 tablets in a cool, dry place where it stays below 30°C.**

Discard any remaining product 30 days after first opening of the bottle.

**Do not store CIPLA TENOFOVIR + EMTRICITABINE 300/200 or any other medicine in a bathroom or near a sink.**

**Do not leave CIPLA TENOFOVIR + EMTRICITABINE 300/200 in the car or on a window sill.**

Heat and dampness can destroy some medicines.

**Keep your CIPLA TENOFOVIR + EMTRICITABINE 300/200 tablets in the bottle with the cap tightly closed until you take them.**

If you take CIPLA TENOFOVIR + EMTRICITABINE 300/200 tablets out of their pack they may not keep well.

##### **Disposal**

If your doctor tells you to stop taking CIPLA TENOFOVIR + EMTRICITABINE 300/200, or the tablets have passed their

expiry date, ask your pharmacist what to do with any tablets left over.

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#### **PRODUCT DESCRIPTION**

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##### ***What the tablets look like***

CIPLA TENOFOVIR + EMTRICITABINE 300/200 tablets are blue coloured capsule shaped, biconvex film coated tablet, plain on both sides.

CIPLA TENOFOVIR + EMTRICITABINE 300/200 tablets are supplied in bottles containing 30 tablets.

##### ***Ingredients***

Each CIPLA TENOFOVIR + EMTRICITABINE 300/200 tablet contains the following active ingredients:

- 300 mg tenofovir disoproxil fumarate equivalent to tenofovir disoproxil 245 mg
- 200 mg emtricitabine

Each CIPLA TENOFOVIR + EMTRICITABINE 300/200 tablet also contains the following inactive ingredients:

- croscarmellose sodium
- lactose monohydrate
- magnesium stearate
- microcrystalline cellulose
- pregelatinised starch

Film-coating:

- hypromellose
- indigo carmine aluminium lake
- lactose monohydrate
- titanium dioxide
- triacetin

##### **SPONSOR**

**CIPLA TENOFOVIR + EMTRICITABINE 300/200 tablets are supplied in Australia by:**

Cipla Australia Pty Ltd.,  
Level 1 / 132-136 Albert road, South  
Melbourne Vic 3205

##### **Australian Registration Number**

AUST R 327898

##### ***Date of preparation***

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