Tenofovir/Emtricitabine Sandoz® 301/200

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Tenofovir/Emtricitabine Sandoz 301/200?

Tenofovir/Emtricitabine Sandoz 301/200 contains the active ingredients tenofovir disoproxil succinate and emtricitabine. Tenofovir/Emtricitabine Sandoz 301/200 is used to help control Human Immunodeficiency Virus (HIV) infection.

For more information, see Section 1. Why am I using Tenofovir/Emtricitabine Sandoz 301/200? in the full CMI.

2. What should I know before I use Tenofovir/Emtricitabine Sandoz 301/200?

Do not use if you have ever had an allergic reaction to tenofovir disoproxil succinate/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 use Tenofovir/Emtricitabine Sandoz 301/200? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Tenofovir/Emtricitabine Sandoz 301/200 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 use Tenofovir/Emtricitabine Sandoz 301/200?

- Take one Tenofovir/Emtricitabine Sandoz 301/200 tablet once daily or as advised by your doctor at the same time each day.

More instructions can be found in Section 4. How do I use Tenofovir/Emtricitabine Sandoz 301/200? in the full CMI.

5. What should I know while using Tenofovir/Emtricitabine Sandoz 301/200?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Tenofovir/Emtricitabine Sandoz 301/200. • Do not miss any doses of Tenofovir/Emtricitabine Sandoz 301/200. • Tell your doctor if you become pregnant while taking this medicine. • Tell your doctor if you for any reason have not taken your medicine exactly as prescribed. • Tell your doctor if you think you were exposed to HIV.
Things you should not do	• Do not stop using this medicine or change the dose without checking with your doctor. • Do not give this medicine to anyone else even if their symptoms seem similar to yours. • Do not use this medicine to treat any other complaints unless your doctor says to.
Driving or using machines	• Be careful before you drive or use any machines until you know how Tenofovir/Emtricitabine Sandoz 301/200 affects you.
Drinking alcohol	• Tell your doctor if you drink alcohol.
Looking after your medicine	• Keep the medicine in a cool dry place where the temperature stays below 25°C. • Keep your capsules in the original pack until it is time to take them.

For more information, see Section 5. What should I know while using Tenofovir/Emtricitabine Sandoz 301/200? in the full CMI.

6. Are there any side effects?

You may experience serious side effects when taking Tenofovir/Emtricitabine Sandoz 301/200.

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/Emtricitabine Sandoz® 301/200

Active ingredient(s): *tenofovir disoproxil succinate / emtricitabine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Tenofovir/Emtricitabine Sandoz 301/200. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Tenofovir/Emtricitabine Sandoz 301/200.**

Where to find information in this leaflet:

1. Why am I using Tenofovir/Emtricitabine Sandoz 301/200?
2. What should I know before I use Tenofovir/Emtricitabine Sandoz 301/200?
3. What if I am taking other medicines?
4. How do I use Tenofovir/Emtricitabine Sandoz 301/200?
5. What should I know while using Tenofovir/Emtricitabine Sandoz 301/200?
6. Are there any side effects?
7. Product details

1. Why am I using Tenofovir/Emtricitabine Sandoz 301/200?

Tenofovir/Emtricitabine Sandoz 301/200 contains the active ingredients tenofovir disoproxil succinate and emtrictaibine. Tenofovir/Emtricitabine Sandoz 301/200 belong to a group of antiviral medicines known as nucleoside and nucleotide reverse transcriptase inhibitors (NRTI).

Tenofovir/Emtricitabine Sandoz 301/200 is used to treat Human Immunideficiency Virus-1 (HIV-1) infection in adults when taken in combination with other anti-HIV medicines and 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/Emtricitabine Sandoz 301/200 is used to treat HIV infection:

When used with other HIV-1 medicines to treat HIV-1 infection, Tenofovir/Emtricitabine Sandoz 301/200 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/Emtricitabine Sandoz 301/200 cure HIV or AIDS:

Tenofovir/Emtricitabine Sandoz 301/200 is not a cure for HIV infection or AIDS. While taking Tenofovir/Emtricitabine Sandoz 301/200 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 Tenofovir/Emtricitabine Sandoz 301/200 reduce the risk of passing HIV to others:

Tenofovir/Emtricitabine Sandoz 301/200 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/Emtricitabine Sandoz 301/200 is used to reduce the risk of HIV infection:

When used with safer sex practices, Tenofovir/Emtricitabine Sandoz 301/200 may help to reduce the risk of getting HIV-1 infection if you are at high risk of getting HIV infection.

Tenofovir/Emtricitabine Sandoz 301/200 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 use Tenofovir/Emtricitabine Sandoz 301/200?

Warnings

Do not use Tenofovir/Emtricitabine Sandoz 301/200 if:

- you are allergic to tenofovir, tenofovir disoproxil succinate or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you are already taking any of the components of Tenofovir/Emtricitabine Sandoz 301/200 (tenofovir disoproxil succinate or emtricitabine).
- you are taking lamivudine.
- you are taking adefovir dipivoxil.

- you are taking tenofovir alafenamide.
- Do not take 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 if the packaging is torn or shows signs of tampering.

Do not use Tenofovir/Emtricitabine Sandoz 301/200 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/Emtricitabine Sandoz 301/200 to treat HIV. Tenofovir/Emtricitabine Sandoz 301/200 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/Emtricitabine Sandoz 301/200 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/Emtricitabine Sandoz 301/200 or at any time while taking Tenofovir/Emtricitabine Sandoz 301/200. 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 liver problems, including hepatitis B, or C virus infection.
- are taking medication to treat your hepatitis C virus (HCV) infection (e.g. ledipasvir/sofosbuvir, sofosbuvir/velpatasvir).
- have kidney problems.
- have or have ever had abnormal bones or bone difficulties.

If you have a long standing viral infection of your liver (hepatitis B) it may flare up when you stop taking Tenofovir/Emtricitabine Sandoz 301/200.

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/Emtricitabine Sandoz 301/200 and even after you stop, your doctor is likely to arrange tests from time to time to check how well your liver is working.

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.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

The safe use of Tenofovir/Emtricitabine Sandoz 301/200 in pregnancy has not been demonstrated. For this reason, it is important that women of child-bearing age receiving treatment with Tenofovir/Emtricitabine Sandoz 301/200 use an effective method of contraception to avoid becoming pregnant.

If you are a female who is taking Tenofovir/Emtricitabine Sandoz 301/200 to reduce the risk of getting HIV-1 infection and you become pregnant while taking Tenofovir/Emtricitabine Sandoz 301/200, talk to your healthcare provider to decide if you should keep taking Tenofovir/Emtricitabine Sandoz 301/200.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

The active substances in this medicine (tenofovir disoproxil succinate 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/Emtricitabine Sandoz 301/200. 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 and elderly

Tenofovir/Emtricitabine Sandoz 301/200 is for adults.

Do not take Tenofovir/Emtricitabine Sandoz 301/200 if you are under the age of 18 years.

Do not take Tenofovir/Emtricitabine Sandoz 301/200 if you are over the age of 65 years before discussing with your doctor.

3. What if I am taking other 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.

If you have HIV infection your doctor will generally prescribe Tenofovir/Emtricitabine Sandoz 301/200 in combination with other anti-HIV medicines.

Some medicines may interfere with Tenofovir/Emtricitabine Sandoz 301/200 and affect how it works. Your doctor or pharmacist will be able to tell you what to do when taking Tenofovir/Emtricitabine Sandoz 301/200 tablets with other medicines.

Tell your doctor if you are taking:

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

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/Emtricitabine Sandoz 301/200.

4. How do I use Tenofovir/Emtricitabine Sandoz 301/200?

How much to take

- Take one Tenofovir/Emtricitabine Sandoz 301/200 tablet once daily or as advised by your doctor. Your doctor will tell you how much to take and how often to take it.
- Tenofovir/Emtricitabine Sandoz 301/200 is best taken with a meal or just afterwards, however taking it without food should not reduce the effectiveness of the medicine.
- Follow the instructions provided and use Tenofovir/Emtricitabine Sandoz 301/200 until your doctor tells you to stop. Do not stop or change you the amount of Tenofovir/Emtricitabine Sandoz 301/200 you take unless advised by your doctor.

Tenofovir/Emtricitabine Sandoz 301/200 is absorbed rapidly. Do not take another Tenofovir/Emtricitabine Sandoz 301/200 dose if vomiting has occurred unless it occurs within 1 hour after taking Tenofovir/Emtricitabine Sandoz 301/200.

Because your medicine helps to control your condition, but does not cure it, you will need to take Tenofovir/Emtricitabine Sandoz 301/200 every day. If you are taking Tenofovir/Emtricitabine Sandoz 301/200 to reduce the risk of HIV-1 infection, take Tenofovir/Emtricitabine Sandoz 301/200 every day for the period of time as prescribed by your doctor.

When to take Tenofovir/Emtricitabine Sandoz 301/200

- Take Tenofovir/Emtricitabine Sandoz 301/200 at the same time each day to keep Tenofovir/Emtricitabine Sandoz 301/200 blood levels constant.

If you forget to use Tenofovir/Emtricitabine Sandoz 301/200

Tenofovir/Emtricitabine Sandoz 301/200 should be used regularly at the same time each day.

If you miss your dose at the usual time, take it as soon as you remember that day, and then go back to taking your medicine as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

Do not take more than one Tenofovir/Emtricitabine Sandoz 301/200 tablet in a day.

If you use too much Tenofovir/Emtricitabine Sandoz 301/200

If you think that you have used too much Tenofovir/Emtricitabine Sandoz 301/200, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), 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 using Tenofovir/Emtricitabine Sandoz 301/200?

Things you should do

Call your doctor straight away if you:

- Become pregnant or are trying to become pregnant.
- For any reason have not taken your medicine exactly as prescribed.
- Think you were exposed to HIV. They 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 using Tenofovir/Emtricitabine Sandoz 301/200.

Do not miss any doses of Tenofovir/Emtricitabine Sandoz 301/200. Missing doses may increase your risk of getting HIV infection.

If you become HIV-positive, you need more medicine than Tenofovir/Emtricitabine Sandoz 301/200 alone to treat HIV. Tenofovir/Emtricitabine Sandoz 301/200 by itself is not a complete treatment for HIV.
If you have HIV and take only Tenofovir/Emtricitabine Sandoz 301/200, over time your HIV may become harder to treat.

Get information and support to help reduce risky sexual behaviour. Have fewer sex partners.

If you are taking Tenofovir/Emtricitabine Sandoz 301/200 to reduce your risk of getting HIV:

- Just taking Tenofovir/Emtricitabine Sandoz 301/200 may not keep you from getting HIV.
- You must continue using safer sex practices while you are taking Tenofovir/Emtricitabine Sandoz 301/200 to reduce your risk of getting HIV.
- You must stay HIV-negative to keep taking Tenofovir/Emtricitabine Sandoz 301/200 to reduce your risk of infection
- Know you 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. Tenofovir/Emtricitabine Sandoz 301/200 will not stop you from getting these other infections.

Things you should not do

- Do not stop using this medicine 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 this medicine 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/Emtricitabine Sandoz 301/200 affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep tablets in a cool, dry place where it stays below 25°C.
- Keep your tablets in the bottle with the cap tightly closed until you taken them. If you take Tenofovir/Emtricitabine Sandoz 301/200 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.

Getting rid of any unwanted medicine

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

Do not use 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.

Less serious side effects

Less serious side effects	What to do
Taking Tenofovir/Emtricitabine Sandoz 301/200 to treat HIV-1 infection: • diarrhoea • nausea • tiredness • headache • dizziness • depression • problems sleeping • abnormal dreams • rash **Taking Tenofovir/Emtricitabine Sandoz 301/200 to reduce the risk of getting HIV-1 infection:** • stomach-area (abdomen) pain • headache • decreased weight	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Allergy: • 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 **Pancreatitis:** • Severe stomach pain or cramps • Nausea • Vomiting	**Do not take any more Tenofovir/ Emtricitabine Sandoz 301/200 and 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.**

Serious Liver Problems (hepatotoxicity):

- 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

Lactic Acidosis (build up of acid in the blood):

- 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

Hepatic Flares:

- Your doctor should test you to see if you have chronic hepatitis B infection before you start taking Tenofovir/Emtricitabine Sandoz 301/200.
  If you have chronic hepatitis B infection you should not stop your Tenofovir/Emtricitabine Sandoz 301/200 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 Tenofovir/Emtricitabine Sandoz 301/200.
  You may require medical exams and blood tests for several months after stopping treatment.
  Tenofovir/Emtricitabine Sandoz 301/200 is not approved for the treatment of hepatitis B, so you must discuss your hepatitis B therapy with your healthcare provider.

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/Emtricitabine Sandoz 301/200. 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.

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. 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/Emtricitabine Sandoz 301/200 contains

Active ingredient	• Tenofovir disproxil succinate 300.6 mg

(main ingredient)	• Emtricitabine 200 mg
Other ingredients (inactive ingredients)	• croscarmellose sodium • lactose monohydrate • magnesium stearate • microcrystalline cellulose • pregelatinised maize starch Film coating: • polyvinyl alcohol • macrogol 3350 • purified talc • indigo carmine aluminium lake (E132) • titanium dioxide (E171)
Potential allergens	Lactose monohydrate

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

What Tenofovir/Emtricitabine Sandoz 301/200 looks like

Tenofovir/Emtricitabine Sandoz 301/200 tablets are blue, capsule-shaped, film-coated and plain on both sides. Tenofovir/Emtricitabine Sandoz 301/200 are supplied in bottles containing 30 tablets (AUST R 326237).

Who distributes Tenofovir/Emtricitabine Sandoz 301/200

Tenofovir/Emtricitabine Sandoz 301/200 is supplied in Australia by:

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia

Tel 1800 726 369

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