

## CONSUMER MEDICINE INFORMATION

### Tenofovir disoproxil tablets (Teva)

Tenofovir disoproxil tablets 245 mg

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#### What is in this leaflet

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Please read this leaflet carefully before you start taking Tenofovir disoproxil tablets (Teva).

This leaflet answers some common questions about Tenofovir disoproxil tablets (Teva). It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Tenofovir disoproxil tablets (Teva) against the benefits they expect it will have for you.

**If you have any concerns about using this medicine, ask your doctor or pharmacist.**

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

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#### What Tenofovir disoproxil tablets (Teva) is used for

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Tenofovir disoproxil tablets (Teva) is an antiviral medication used to treat two different viruses; Chronic Hepatitis B (CHB) and Human Immunodeficiency Virus (HIV) Infection.

Tenofovir disoproxil tablets (Teva) is a type of medicine called a HBV polymerase inhibitor and a nucleotide analog reverse transcriptase inhibitor (NRTI).

#### How Tenofovir disoproxil tablets (Teva) work in the treatment of CHB

Tenofovir disoproxil tablets (Teva) are used to treat CHB (an infection with hepatitis B virus [HBV]) in adults and paediatric patients aged 12 years and older and weighing at least 35 kg.

Tenofovir disoproxil tablets (Teva) work by interfering with the normal working of enzymes (HBV DNA polymerase) that are essential for HBV to reproduce itself. Tenofovir disoproxil tablets (Teva) may help lower the amount of hepatitis B virus in your body by lowering the ability of the virus to multiply and infect new liver cells and can improve the inflammation and scar tissue caused by the hepatitis B virus in your liver.

Lowering the amount of virus in your body may reduce the chance of developing cirrhosis, liver failure and liver cancer.

We do not know how long Tenofovir disoproxil tablets (Teva) may help treat your hepatitis. Sometimes viruses change in your body and medicines no longer work. This is called drug resistance.

### **How Tenofovir disoproxil tablets (Teva) work in the treatment of HIV-infection**

Tenofovir disoproxil tablets (Teva) is also used to treat HIV infection in adults and paediatric patients aged 12 years and older and weighing at least 35 kg. Tenofovir disoproxil tablets (Teva) is always used in combination with other anti-HIV medicines to treat people with HIV-1 infection.

HIV infection destroys CD4 (T) cells, which are important to the immune system. After a large number of T cells are destroyed, acquired immune deficiency syndrome (AIDS) develops.

Tenofovir disoproxil tablets (Teva) helps to block HIV-1 reverse transcriptase, a chemical (enzyme) in your body that is needed for HIV-1 to multiply. Tenofovir disoproxil tablets (Teva) lowers the amount of HIV-1 in the blood (called viral load) and may help to increase the number of T cells (called CD4 cells). Lowering the amount of HIV-1 in the blood lowers the chance of death or infections that happen when your immune system is weak (opportunistic infections).

You do not have to have HIV infection to be treated with Tenofovir disoproxil tablets (Teva) for HBV and vice versa.

### **Tenofovir disoproxil tablets (Teva) does not cure HIV infection or AIDS.**

The long-term effects of Tenofovir disoproxil tablets (Teva) are not known at this time. People taking Tenofovir disoproxil tablets (Teva) may still get opportunistic infections or other conditions that happen with HIV-1 infection. Opportunistic infections are infections that develop because the immune system is weak. Some of these conditions are:

- pneumonia,
- herpes virus infections, and
- *Mycobacterium avium complex* (MAC) infection.

**Tenofovir disoproxil tablets (Teva) does not reduce the risk of passing HIV-1 or HBV to others through sexual contact or blood contamination.**

**Continue to practice safe sex and do not use or share dirty needles.**

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## **Before you take Tenofovir disoproxil tablets (Teva)**

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### ***Who must not take it***

**Together with your doctor, you need to decide whether Tenofovir disoproxil tablets (Teva) is right for you.**

**Do not take Tenofovir disoproxil tablets (Teva) if you are allergic to any of the ingredients listed at the end of this leaflet under the heading Product Description.**

**Do not take Tenofovir disoproxil tablets (Teva) if you are already taking any other medicines that contain the same active ingredients.**

**Do not take Tenofovir disoproxil tablets (Teva) if you are already taking adefovir dipivoxil to treat hepatitis B virus (HBV) infection.**

**Do not take Tenofovir disoproxil tablets (Teva) if you are already taking tenofovir alafenamide to treat HIV or hepatitis B virus (HBV) infection.**

***Before you start to take it***

Tell your doctor if:

- you are pregnant or planning to become pregnant. The effects of Tenofovir disoproxil tablets (Teva) on pregnant women or their unborn babies is unknown.
- you are breastfeeding. Do not breastfeed if you are taking Tenofovir disoproxil tablets (Teva). The active substance in this medicine (tenofovir disoproxil succinate) has been found in breast milk at low concentrations. Do not breast-feed if you have HIV or HBV. If you are a woman who has or will have a baby, talk with your doctor or pharmacist about the best way to feed your baby. If your baby does not already have HIV or HBV, there is a chance that the baby can get HIV or HBV through breast-feeding.
- you have kidney problems.
- you have bone problems.
- you liver problems, including HBV and hepatitis C virus (HCV).
- you have HIV infection.

Tell your doctor or pharmacist about all your medical conditions.

***Taking other medicines***

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Tenofovir disoproxil tablets (Teva).

Some medicines may interfere with Tenofovir disoproxil tablets (Teva). These include:

- Harvoni (ledipasvir/sofosbuvir) or Epclusa (sofosbuvir/velpatasvir) to treat your HCV infection. These medicines may increase the amount of Tenofovir disoproxil tablets (Teva) in your blood, which could result in additional or more intense side effects (see Side Effects).
- Videx/Videx EC (didanosine); Tenofovir disoproxil tablets (Teva) may increase the amount of Videx in your blood. You may need to be followed more carefully if you are taking Videx and Tenofovir disoproxil tablets

(Teva) together. If you are taking Videx and Tenofovir disoproxil tablets (Teva) together, your doctor may need to reduce your dose of Videx.

- Reyataz (atazanavir sulfate) or Kaletra (lopinavir/ritonavir); These medicines may increase the amount of Tenofovir disoproxil tablets (Teva) in your blood, which could result in more side effects (see Side Effects). You may need to be followed more carefully if you are taking Tenofovir disoproxil tablets (Teva) and Reyataz or Kaletra together. Tenofovir disoproxil tablets (Teva) may decrease the amount of Reyataz in your blood. If you are taking Tenofovir disoproxil tablets (Teva) and Reyataz together you should also be taking Norvir (ritonavir).

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Tenofovir disoproxil tablets (Teva).

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## **How to take Tenofovir disoproxil tablets (Teva)**

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Stay under a doctor's care when taking Tenofovir disoproxil tablets (Teva).

Do not change your treatment or stop treatment without first talking with your doctor.

Take Tenofovir disoproxil tablets (Teva) exactly as your doctor prescribed it.

Follow the directions from your doctor or pharmacist, exactly as written on the label.

Set up a dosing schedule and follow it carefully.

### ***How much to take***

The usual dose of Tenofovir disoproxil tablets (Teva) is one tablet once a day.

If you have kidney problems, your doctor may recommend that you take Tenofovir disoproxil tablets (Teva) less frequently.

### ***How to take it***

Tenofovir disoproxil tablets (Teva) is best taken with a meal or just afterwards, however taking it without food should not reduce the effectiveness of the medicine.

If you are taking Tenofovir disoproxil tablets (Teva) to treat HIV or if you have HIV and HBV coinfection and are taking Tenofovir disoproxil tablets (Teva), always take Tenofovir disoproxil tablets (Teva) in combination with other anti-HIV medicines.

Tenofovir disoproxil tablets (Teva) and other medicines like Tenofovir disoproxil tablets (Teva), may be less likely to work in the future if you are not taking Tenofovir disoproxil tablets (Teva) with other anti-HIV medicines because you may develop resistance to those medicines. If you have any questions about what medicines you should or should not be taking, please see your doctor or pharmacist.

If you have been given Tenofovir disoproxil tablets (Teva) to treat CHB, you are advised to get a HIV test before you start taking Tenofovir disoproxil tablets (Teva) and at any time after that when there is a chance you were exposed to HIV.

**When your Tenofovir disoproxil tablets (Teva) supply starts to run low, get more from your doctor or pharmacist.**

This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to Tenofovir disoproxil tablets (Teva), and may become harder to treat. If you are taking Tenofovir disoproxil tablets (Teva) to treat CHB, stopping treatment may result in very severe hepatitis and serious liver problems (see Side Effects).

**Only take medicine that has been prescribed specifically for you.**

**Do not give Tenofovir disoproxil tablets (Teva) to others or take medicine prescribed for someone else.**

***If you forget to take it***

**It is important that you do not miss any doses.**

**If you miss a dose of Tenofovir disoproxil tablets (Teva), take it as soon as possible and then take your next scheduled dose at its regular time.**

**If it is almost time for your next dose, do not take the missed dose. Wait and take the next dose at the regular time. Do not double the next dose.**

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## **While you are taking Tenofovir disoproxil tablets (Teva)**

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### ***Things you must not do***

Do not breast feed. See "Before you start to take it".

### ***Things to be careful of***

Some patients taking Tenofovir disoproxil tablets (Teva) have experienced dizziness. Make sure you know how you react to Tenofovir disoproxil tablets (Teva) before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy.

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

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**Immediately telephone your doctor or the National Poisons Information Centre (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 tablets (Teva) tablets. Do this even if there are no signs of discomfort or poisoning. This may need urgent medical attention.**

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## Side effects

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In clinical studies in patients with HIV the most common side effects of Tenofovir disoproxil tablets (Teva) are:

- diarrhoea
- nausea
- vomiting
- dizziness

Less common side effects of Tenofovir disoproxil tablets (Teva) are:

- flatulence (intestinal gas)

In clinical studies in patients with CHB the only common side effect of Tenofovir disoproxil tablets (Teva) is:

- nausea

Marketing experience has shown other side effects reported since Tenofovir disoproxil tablets (Teva) has been marketed include:

- allergic reaction
- low blood phosphate
- shortness of breath
- increased liver enzymes
- increased amylase
- inflammation of the liver
- stomach pain
- inflammation of the pancreas
- rash
- weakness

Tenofovir disoproxil tablets (Teva) may cause the following other side effects:

### **Kidney Problems**

Some patients treated with Tenofovir disoproxil tablets (Teva) have had kidney problems. If you have had kidney problems in the past or need to take another drug that can cause kidney problems, your doctor may need to perform additional blood tests. Kidney problems may be associated with muscle problems and softening of the bones.

### **Changes in Bone Mineral Density**

Laboratory tests show changes in the bones of patients treated with Tenofovir disoproxil tablets (Teva). It is not known whether long-term use of Tenofovir disoproxil tablets (Teva) will cause damage to your bones. If you have had bone problems in the past, your doctor may need to perform additional tests or may suggest additional medication.

## **Lactic Acidosis**

Some patients taking antiviral drugs like Tenofovir disoproxil tablets (Teva) have developed a condition called lactic acidosis (a build-up in the blood of lactic acid, the same substance that causes your muscles to burn during heavy exercise). Symptoms of lactic acidosis include nausea, vomiting, unusual or unexpected stomach discomfort, and weakness.

**If you notice these symptoms or if your medical condition changes suddenly, call your doctor right away.**

## **Changes in body fat**

Changes in body fat have been seen in some patients taking anti-HIV medicine. These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the main part of your body (trunk). Loss of fat from the legs, arms and face may also happen. The cause and long term health effects of these conditions are not known at this time.

## **Hepatic Flares**

It is extremely important that you do not stop taking Tenofovir disoproxil tablets (Teva) without your doctor’s advice. If you have Hepatitis B infection or HIV and HBV infection together, you may have a “flare-up” of Hepatitis B if you stop taking Tenofovir disoproxil tablets (Teva), where the disease suddenly returns in a worse way than before. This flare-up may lead to liver failure and possibly liver transplantation or death.

After stopping Tenofovir disoproxil tablets (Teva), tell your doctor immediately about any new, unusual, or worsening symptoms that you notice after stopping treatment.

After you stop taking Tenofovir disoproxil tablets (Teva), your doctor will still need to check your health and take blood tests to check your liver for several months.

There have been other side effects in patients taking Tenofovir disoproxil tablets (Teva).

However, these side effects may have been due to other medicines that patients were taking or to the illness itself.

Some of these side effects can be serious.

This list of side effects is not complete. If you have questions about side effects, ask your doctor or pharmacist.

You should report any new or continuing symptoms to your doctor or pharmacist right away.

Your doctor or pharmacist may be able to help you manage these side effects.

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## **After taking Tenofovir disoproxil tablets (Teva)**

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### ***Storage***

Keep your Tenofovir disoproxil tablets (Teva) in the bottle until it is time to take them.

Store below 25°C and out of reach of children. Avoid exposure to heat, light and moisture.

Do not store Tenofovir disoproxil tablets (Teva), or any other medicine, in the bathroom or near a sink.

### ***Disposal***

If your doctor tells you to stop taking Tenofovir disoproxil tablets (Teva) or if the tablets have passed the expiry date, ask your pharmacist what to do with the remaining medicine.

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## **Product Description**

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

Tenofovir disoproxil tablets (Teva) are light blue, almond shaped, film coated tablets with dimensions of approximately 17.0 mm x 10.5 mm.

### ***Ingredients***

#### **Tablet Core**

Lactose, microcrystalline cellulose, pregelatinised maize starch, croscarmellose sodium, magnesium stearate.

#### **Tablet Coating**

Indigo carmine aluminium lake, titanium dioxide, polyvinyl alcohol, macrogol (E1521) and talc.

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## **Sponsor details**

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Tenofovir disoproxil tablets (Teva) is supplied in New Zealand by:

Teva Pharma (New Zealand) Limited  
PO Box 128 244  
Remuera  
Auckland 1541  
Telephone: 0800 800 097

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## **Date of Preparation**

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19 April 2018  
(Based on the data sheet dated 1 February 2018)