

# Truvada

## Summary

Truvada is the name of a fixed-dose co-formulation of two anti-HIV drugs: tenofovir and FTC all in one pill. Truvada is used as part of combination therapy for people with HIV. Some doctors may also prescribe Truvada to HIV-negative people as part of a package of HIV prevention tools to help reduce the risk of HIV transmission. Truvada is generally well-tolerated. Common side effects of Truvada can include dizziness, headache, nausea and vomiting. Truvada is taken once-daily with or without food.

## What is Truvada?

Truvada is the brand name of a fixed-dose co-formulation of two anti-HIV drugs: tenofovir (Viread) and FTC (emtricitabine) all in one pill. Generic formulations are also available.

## How does Truvada work?

When HIV infects a cell, it takes control of that cell. HIV then forces the cell to make many more copies of the virus. To make these copies, the cell uses proteins called enzymes. When the activity of these enzymes is reduced the production of HIV slows.

The two medications inside Truvada are as follows:

- Tenofovir DF – this belongs to a group or class of drugs called nucleotide analogues (“nukes”)
- FTC – this belongs to a group of drugs called nucleoside analogues (“nukes”)

Both medicines inside Truvada interfere with an enzyme called reverse transcriptase, which is used by HIV-infected cells to make new viruses. Since Truvada reduces the activity of reverse transcriptase, it causes HIV-infected cells to slow down or stop producing new viruses.

Truvada, when taken as part of a package of HIV prevention tools (frequent screening for HIV and other sexually transmitted infections, safer sex counselling, use of condoms), can significantly reduce the risk of HIV transmission in some people. For more information about this, see CATIE’s fact sheet *Oral pre-exposure prophylaxis (PrEP)*.

# FACT SHEET

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## How do people with HIV use Truvada?

Truvada is taken in combination with other anti-HIV drugs including non-nukes (NNRTIs), protease inhibitors or integrase inhibitors. Such combinations are called antiretroviral therapy, or ART. For more information on ART, see CATIE's *Your Guide to HIV Treatment*.

Neither Truvada nor any other anti-HIV medication is a cure for HIV. It is therefore important that you see your doctor regularly so that he/she monitors your health.

Evidence shows that HIV-positive people who are on ART, engaged in care, and have an ongoing undetectable viral load are substantially less likely to transmit HIV to others, be it through sex, when sharing equipment to use drugs or during pregnancy and birth. In fact, the evidence for sexual transmission shows that people on ART who maintain an undetectable viral load do not pass HIV to their sexual partners. For further information see the CATIE fact sheet *HIV treatment and an undetectable viral load to prevent HIV transmission*. However, it is still a good idea to use condoms because they can reduce your risk for getting and passing on other sexually transmitted infections.

## How do people who are HIV negative use Truvada as PrEP?

HIV-negative people can take Truvada to reduce their risk of becoming infected with HIV. People taking Truvada as PrEP as part of a package of HIV prevention tools should be tested for HIV and other sexually transmitted infections every three months and also receive safer sex and adherence counselling if needed. For healthcare professionals interested in prescribing Truvada as PrEP, see *Canadian guidelines on HIV pre-exposure prophylaxis and nonoccupational postexposure prophylaxis*.

## Warnings

### 1. Lactic acidosis

Higher-than-normal levels of lactic acid can occur in the blood. This condition is called lactic acidosis

and has happened in some HIV-positive people who have used tenofovir, FTC or related anti-HIV drugs. Women who are overweight are at increased risk for lactic acidosis. Sometimes the livers of people with lactic acidosis become swollen because of fatty deposits. Signs and symptoms of lactic acidosis may include the following:

- nausea
- vomiting
- abdominal pain
- diarrhea
- unexpected tiredness
- unexpected muscle pain
- feeling cold especially in the arms and legs
- feeling dizzy or light-headed

If these symptoms persist, see your doctor right away.

### 2. Hepatitis B

Truvada contains tenofovir and FTC. Both of these drugs have anti-hepatitis B virus (HBV) activity. People with an HBV infection who take Truvada and then later stop may experience worsening HBV infection (commonly called "flares"). People who are co-infected with HIV and hepatitis-causing viruses and who take ART are sometimes at increased risk for liver injury. It is important to have regular blood tests so that your doctor can assess the health of your liver.

If you have HBV infection, talk to your doctor before you start Truvada. If you are not sure if you have HBV, ask your doctor about getting tested. If you later need to change your therapy from Truvada, remind your doctor that you have HBV. If lab tests reveal that you do not have HBV, speak to your doctor about getting a vaccine to protect you from HBV.

### 3. Pancreatitis

Painfully swollen pancreas glands have been reported in some people taking tenofovir as part of ART. Higher-than-normal levels in the blood of the

enzyme amylase (made by the pancreas gland) have been detected in some people taking tenofovir. This increase may be suggestive of inflammation in the pancreas gland. Symptoms of pancreatitis can include the following:

- abdominal pain, particularly when laying down
- nausea
- vomiting
- unexpected sweating
- fever
- anxiety

If these symptoms occur, talk to your doctor right away.

#### 4. Kidney injury

Tenofovir DF can cause kidney dysfunction and injury. If you or a close family member have kidney problems, tell your doctor. For more about tenofovir and the kidneys, please see the section on side effects later in this fact sheet.

### Side effects

#### 1. General side effects

Truvada is generally well-tolerated. In some cases, temporary side effects such as the following may occur:

- dizziness
- headache
- nausea
- vomiting
- flatulence

If these persist, speak to your doctor.

#### 2. Kidney health

Truvada contains a formulation of tenofovir called tenofovir DF, and this drug belongs to a group of drugs called nucleotide analogues. This group of drugs is broken down by the kidneys and is

associated with kidney dysfunction. There have been reports of cases of kidney dysfunction in some people who used tenofovir. People who use this drug may wish to have regular blood and urine tests done so that their doctors can assess the health of their kidneys. These tests can include the following:

- creatinine
- e-GFR (estimated-glomerular filtration rate)
- calcium
- phosphorus or phosphate
- bicarbonate

In addition to tenofovir, there are other medications which are processed by the kidneys and have the potential to cause or amplify kidney dysfunction. Many of these medications are antibiotics and are grouped as follows:

- beta-lactams – penicillin, amoxicillin
- quinolones – ciprofloxacin and related compounds
- aminoglycosides – amikacin, gentamicin
- macrolides – erythromycin
- tetracyclines – minocycline
- anti-tuberculosis agents – rifampin, ethambutol
- other antibiotics – co-trimoxazole (Septra/Bactrim), vancomycin (Vanocin), linezolid

Bear in mind that there are other medications with the potential to cause kidney dysfunction. The following is a list of medications with this potential, but this list is not exhaustive:

- antiviral agents – acyclovir (Zovirax), valacyclovir (Valtrex), cidofovir (Vistide), foscarnet (Foscavir), indinavir (Crixivan)
- antifungal agents – amphotericin B (Fungizone), intravenous pentamidine
- anti-seizure drugs – phenytoin, carbamazepine, valproic acid, phenobarbital

- medicines to treat pain and inflammation – acetaminophen (Tylenol), ibuprofen (Advil, Motrin), indomethacin (Indocid), naproxen (Naprosyn), celecoxib (Celebrex), meloxicam (Mobic)
- proton pump inhibitors – omeprazole (Losec), esomeprazole (Nexium), pantoprazole (Pantoloc), rabeprazole (Pariet)
- street drugs – use of cocaine has also been linked to kidney injury

### 3. Bone health

Truvada contains tenofovir. In experiments on monkeys using tenofovir at doses 10 to 30 times greater than would be used in people, the animals' bones became thinner over a period of one year.

Before you start taking tenofovir, tell your doctor if you have bone problems or thinner-than-normal bones (osteopenia or osteoporosis).

In clinical trials of regimens containing tenofovir in people with HIV, thinner bones in the spine and elsewhere have occurred. Thinner bones are generally weaker and are at increased risk for breaking (fractures) should accidents or trauma occur.

Researchers are not certain why bone thinning may occur in some people exposed to tenofovir. One theory is that bones became thinner because tenofovir may have injured the kidneys. The kidneys filter blood, putting waste materials into the urine and returning nutrients back to the blood. In the cases of tenofovir-associated bone loss, damaged kidneys may not be able to restore bone-building nutrients back to the blood.

An analysis with data from several thousand HIV-positive people has found that when boosting agents, such as cobicistat or ritonavir were used in regimens containing tenofovir DF, there was a statistically increased risk for thinning bones, bone fractures and kidney injury. Ritonavir is sold under the brand name Norvir and in generic formulations. It is also found in a medicine called Kaletra (lopinavir + ritonavir). Cobicistat is sold as Tyboost and is found with tenofovir DF in the combination tablet Stribild.

Bear in mind that some people can develop thinner-than-normal bones without ever using tenofovir. It may be useful for you to discuss with your doctor the possibility of having bone density assessments done before you begin taking tenofovir or any other anti-HIV therapy. If your bones are thin, your doctor may suggest that you increase your intake of calcium and vitamin D<sub>3</sub>. Regular monitoring of bone density may also be useful.

Risk factors for thinning bones include the following:

- smoking tobacco
- excessive intake of alcohol
- not enough calcium in the diet
- not enough vitamin D in the blood
- being thinner than normal (having a less than ideal body mass index)
- severe kidney or liver disease
- in men low testosterone levels
- women who are undergoing menopause or who are post-menopausal, as the amount of estrogen in the body decreases during these transitions

In addition, there are many medicines that can in some cases, reduce bone density including the following groups of drugs:

- antiseizure medicines
- antidepressants
- proton pump inhibitors (used to reduce stomach acid)
- some transplant medicines including cyclosporine (Neoral) and tacrolimus (Prograf)
- steroids (corticosteroids, glucocorticoids) such as prednisone when used orally for more than three consecutive months

(For more information about vitamin D and bones, see CATIE's *A Practical Guide to Nutrition for People Living with HIV* and *A Practical Guide to a Healthy Body for People Living with HIV*.)

#### 4. Pregnancy

Limited studies in pregnant women and animals suggest that Truvada does not appear to increase the risk of birth defects in the fetus.

The manufacturer recommends that Truvada “should be used in pregnant women only if the potential benefits outweigh the potential risks to the fetus.”

#### 5. Skin discolouration

In very rare cases, darker skin has developed on the palms and the soles of the feet in people exposed to FTC. The reason for this is not clear. However, this side effect does not appear to be harmful.

#### Drug interactions

Always consult your doctor and pharmacist about taking any other prescription or non-prescription medication, including herbs, supplements, and street drugs.

Some drugs can interact with tenofovir or FTC, increasing or decreasing their levels in your body. Increased drug levels can cause you to experience side effects or make pre-existing side effects worse. On the other hand, if drug levels become too low, HIV can develop resistance and your future treatment options may be reduced.

It may also be necessary to avoid drugs that do not affect levels of the medications contained in Truvada, but cause similar side effects.

If you must take a drug that has the potential to interact with your existing medications, your doctor can do the following:

- adjust your dose of either anti-HIV drugs or other medications
- prescribe different anti-HIV drugs for you

#### Drug interactions with Truvada

The following lists contain drugs that interact or have the potential to interact with the medications in Truvada (tenofovir and FTC). These lists are not exhaustive.

The manufacturer recommends that caution be used with the following drugs as there is the potential for serious drug interactions:

- atazanavir (Reyataz) + ritonavir (in Norvir and generic formulations)
- lopinavir/ritonavir (in Kaletra and generic formulations)
- darunavir (Prezista and in Prezcofix)

#### Resistance and cross-resistance

Over time, as new copies of HIV are made in the body, the virus changes its structure. These changes are called mutations and can cause HIV to resist the effects of anti-HIV drugs, which means those drugs will no longer work for you. Combining Truvada with at least one other anti-HIV drug, such as a non-nuke, integrase or protease inhibitor, can significantly delay or prevent the development of drug resistance.

To reduce the risk of developing drug resistance, all anti-HIV drugs should be taken every day exactly as prescribed and directed. If doses are delayed, missed, or not taken as prescribed, levels of tenofovir DF and FTC in the blood may fall too low. If this happens, a drug resistant strain of HIV can develop. If you miss doses when taking Truvada as PrEP, you may increase the risk of becoming infected with a strain of HIV that may be resistant to the drugs in Truvada. If you find you are having problems taking your medications as directed, speak to your doctor and nurse about this. They can find ways to help you.

When HIV becomes resistant to one drug in a class, it sometimes becomes resistant to other drugs in that class. This is called cross-resistance. Feel free to talk with your doctor about your current and future treatment options. To help you decide what these future therapies might be, at some point your doctor can have a small sample of your blood analysed using resistance testing.

Should HIV in your body become resistant to the medicines in Truvada, your doctor, with the help of resistance testing, can help put together a new treatment regimen for you.

## Dosage and formulations

Truvada is available as tablets, each containing 200 mg FTC and 300 mg tenofovir. The standard adult dose of Truvada is one tablet daily, with or without food, in combination with other anti-HIV medications. When used as part of a package of HIV prevention tools, the standard dose of Truvada is one tablet once daily, taken every day. Truvada is also available in generic formulations. Like all medicines, Truvada should always be taken as prescribed and directed.

## Availability

Truvada is licensed in Canada for the treatment of HIV infection in adults, in combination with other anti-HIV drugs. In February 2016, Health Canada also licensed Truvada for HIV prevention when used as part of a package of HIV prevention tools. CATIE's online module *Federal, Provincial and Territorial Drug Access Programs* also contains information about Canadian drug coverage.

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## Disclaimer

Decisions about particular medical treatments should always be made in consultation with a qualified medical practitioner knowledgeable about HIV- and hepatitis C-related illness and the treatments in question.

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