

# Dovato

## Summary

Dovato is a pill containing two medicines—dolutegravir and 3TC (lamivudine). Dolutegravir belongs to the class of drugs called integrase inhibitors. 3TC belongs to a class of drugs called nucleoside analogues (“nukes”). Dovato is taken at a dose of one pill once daily with or without food. Overall, Dovato was well-tolerated in clinical trials and is highly effective. General side effects were uncommon and included headache and tiredness; these were usually mild and temporary.

## What is Dovato?

Dovato contains two medicines—dolutegravir and 3TC (lamivudine). Dolutegravir belongs to the class of drugs called integrase inhibitors. 3TC belongs to the class of drugs called nucleoside reverse transcriptase inhibitors (“nukes”).

## How does Dovato work?

The drugs in Dovato work by interfering with enzymes needed by HIV called integrase and reverse transcriptase. Using Dovato greatly reduces HIV’s ability to infect cells and make copies of itself.

## How do people with HIV use Dovato?

Dovato is considered a complete treatment for people with HIV who are adults or adolescents (12 years and older) who weigh at least 40 kg. Some doctors prescribe Dovato as the initial therapy for HIV infection, while other doctors prescribe Dovato for people who wish to use a simpler regimen. Dovato can be taken with or without food.

ViiV states: “Dovato is not recommended for patients with any known or suspected viral resistance to dolutegravir or [3TC].” ViiV also notes that “the safety and efficacy of Dovato have not been studied in [people with HIV whose previous regimens have failed] and who are currently not virologically suppressed.”

For more information about HIV treatment, see CATIE’s *Your Guide to HIV Treatment*.

# FACT SHEET

Updated  
2025

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For many people with HIV, the use of ART (HIV treatment or antiretroviral therapy) has increased their CD4+ cell counts and decreased the amount of HIV in their blood (viral load). These beneficial effects help to greatly reduce the risk of developing a life-threatening infection or an AIDS-related cancer. Neither Dovato nor any other treatment regimen (ART) is a cure for HIV. It is therefore important that you see your doctor for checkups and lab tests on a regular basis.

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.

## Warnings

### Pregnancy

In May 2018, regulatory agencies, including Health Canada, the U.S. Food and Drug Administration and the European Medicines Agency, issued cautionary statements because dolutegravir was associated with an apparent increased risk of birth defects in a clinical trial in the southern African country of Botswana. Specifically, HIV-positive women who used dolutegravir at the time of conception appeared to have a small but increased risk of giving birth to infants with a type of birth defect called a neural tube defect. This risk was greater than seen when women used other anti-HIV treatments.

However, long-term data have not found an increased risk of birth defects associated with the use of dolutegravir-containing regimens outside of Botswana, including other African countries and in Canada. Furthermore, the number of children born

with such birth defects in Botswana to women who used dolutegravir was limited. Also, over the course of several years in the same study, among women who used dolutegravir at the time of conception, the risk of giving birth to an infant with a birth defect fell.

The good news is that the latest data from Botswana indicate the level of birth defects in infants born to women who use dolutegravir at the time of conception is now very low and similar to that seen in women who use other anti-HIV drugs at the time of conception.

If you are taking Dovato and are pregnant or want to have a baby, let your doctor know.

### Anxiety and depression

Although not common in clinical trials, a small proportion of people (less than 2%) who took dolutegravir-containing medicines developed depression, negative thoughts, anxiety and in some cases, thoughts of self-harm. Some people who had suicidal thoughts attempted suicide.

Anxiety and depression are relatively common in HIV-positive people (regardless of whether they are on treatment or the type of treatment that they take). If you are taking Dovato and think that you may have developed anxiety or depression, speak to your doctor right away. Your doctor can help determine if you have anxiety or depression and if there is any relationship between them and the medicines that you are taking.

Symptoms of anxiety and depression can include the following:

- becoming easily upset or angry
- feeling fearful
- excessive worry
- difficulty falling asleep or staying asleep, or waking up prematurely
- unexpected feelings of sadness
- recurrent nightmares
- prolonged feelings of sadness or anger

- feeling hopeless
- loss of pleasure in everyday activities
- unexpectedly feeling tired or experiencing a lack of energy
- strange thoughts

If you have any of these feelings, contact your doctor or nurse right away.

If you have thoughts of harming yourself or others, dial 911 right away.

### Liver health

There have been cases of liver injury occurring in some people who have used dolutegravir-containing regimens. The reason for liver injury in these cases is not known because none of the people affected had any obvious underlying liver condition or infection.

Some people with HIV are also co-infected with hepatitis B virus (HBV). This virus infects the liver and injures this organ. If you have HBV, speak to your doctor about treatment options. Dovato contains 3TC. This latter drug has activity against HBV. If you stop taking Dovato your HBV may get worse. If you want to stop taking Dovato and have HBV, speak to your doctor about your options to keep HBV under control.

### Age

Dovato has not been tested in people younger than 18 years. However, clinical trials have taken place with combination HIV treatment that included dolutegravir or 3TC in adolescents. These drugs were found to be safe in this population.

### Side effects

#### General

In clinical trials, Dovato was well tolerated, generally safe and effective. However, as with any treatment, there were side effects but these were uncommon,

generally mild and temporary and included the following:

- headache
- nausea
- tiredness

Note that the HIV-positive people who are typically enrolled in pivotal clinical trials of HIV treatments, including Dovato, are generally young and healthy. Once a drug is approved and more widely available, it gets used by populations who are not usually in pivotal clinical trials. These people may be older and may have other health issues—such as cardiovascular disease, liver injury, kidney injury, type 2 diabetes, anxiety, depression, and substance use—that require medications or that cause symptoms. As a result, their experience of side effects may be different from those reported in pivotal clinical trials.

### The kidneys

The kidneys filter the blood, put waste materials into urine and reabsorb nutrients and other useful materials back into the blood. Dovato contains dolutegravir and this drug can interfere with the ability of the kidneys to release the waste product creatinine into urine. Therefore, a small but persistent increase of creatinine levels in the blood is generally seen in dolutegravir users. This small increase is not considered harmful. Furthermore, this effect on creatinine does not appear to affect the ability of the kidneys to filter other substances. Such an effect on creatinine is also seen with the anti-ulcer drug cimetidine (Tagamet) and with the boosting agent cobicistat (found in Genvoya and Stribild) and with the integrase inhibitor bictegravir (in Biktarvy).

ViiV recommends that Dovato should not be used in people who have a creatinine clearance less than 50 mL per minute.

### Weight gain

Research suggests that some people with the following features or characteristics tend to gain

weight when on ART (including dolutegravir-containing regimens):

- women
- people of African, Black or Caribbean descent
- people whose CD4+ cell count fell below the 200 cell/mm<sup>3</sup> level at some point in the past.

However, some HIV-positive people without these features can also gain weight while on dolutegravir-containing regimens. The cause of increased weight in HIV-positive people is not always clear because studies suggest that HIV-negative people of the same age and gender are also generally gaining weight even though they are not taking ART.

An increase of one or two kilograms in weight over the course of one year is normal when initiating ART. However, should you gain more than this amount of weight, speak to your nurse or doctor so that your weight gain can be assessed. Doctors and nurses also consider a person's waist size and/or body mass index (BMI)—this is a number derived by dividing their height by the square of their weight. If your nurse or doctor has found that your BMI is increasing and is outside what is considered healthy then they will investigate possible causes for an increase in weight.

There may be one or more reasons that your BMI is increasing, including the following:

*Physical activity* – Are you getting enough daily physical activity, including walking and climbing stairs? If not, can you begin a program of exercise? Speak to your nurse or doctor about what kind of exercise is right for you.

*Sleeping problems* – Rest and sleep quality are sometimes overlooked aspects of health. A large observational study in HIV-negative people found that people who have sleeping problems tend to gain weight. If you are unexpectedly gaining weight, speak to your doctor or nurse to rule out any sleep problems.

*Emotional and mental health* – Are there factors in your life that can affect how you respond to stressful events? For instance, when stressed, some people eat more fat and carbohydrate-rich foods as a source of comfort. Repeated engagement in excessive intake of carbohydrates and fatty foods

can lead to weight gain over time. Depression can affect appetite—some people gain weight, others lose weight. If you notice weight gain along with changes in your mood, speak to your doctor or nurse.

### Metabolic conditions, hormones and arthritis

Some conditions and life-stages are associated with weight gain, including the following:

- diabetes
- problems with the thyroid gland and its hormones
- being post-menopausal
- arthritis

### Diet

Not everyone follows a diet that is informed by dietary guidelines. If you have access to subsidized dietary counselling (sometimes this is provided in large hospitals and clinics), you may benefit from consulting a registered dietitian. Registered dietitians can assess the quality and quantity of meals, and if necessary, provide helpful advice about making healthy changes.

### Substance use

Alcohol contains calories. Is excess consumption of alcohol an issue for you? Excess consumption of alcoholic beverages could suggest unaddressed mental health and emotional issues. Use of cannabis may also increase appetite and regular use may contribute to weight gain.

### Prescription medicines

Some prescription medicines (for conditions other than HIV) have the potential to cause changes in weight, particularly increased weight. It can be useful to speak to a pharmacist about all the medicines that you are taking to see if any are associated with changes in weight. You can then discuss any medicines that your pharmacist has identified with your doctor.

## Bear in mind

While this list covers some potential causes of weight gain in HIV-positive people, it is not exhaustive.

## Uncommon symptoms

The following symptoms were uncommon in clinical trials, affecting less than 2% of dolutegravir users; it is not clear if these symptoms were caused by dolutegravir, the underlying disease process or something else:

- lack of energy
- nausea
- vomiting
- muscle soreness
- decreased appetite
- feeling sleepy during the daytime

## Drug interactions

Some drugs (including prescribed and over-the-counter), herbs and supplements can interfere with the absorption and/or effectiveness of Dovato. Such interference is called a drug interaction. Some drugs can reduce the levels of the medicines in Dovato in your blood. This can make Dovato less effective and lead to treatment failure, reducing your future treatment options. Other drugs can raise the levels of medicines in Dovato in your blood, resulting in enhanced side effects or new side effects. Therefore, it is important to disclose to your doctor and pharmacist all the supplements, drugs, and herbs you are taking.

This factsheet is not comprehensive and only lists some of the potential and actual drug interactions with Dovato. Speak to your pharmacist to find out more about drug interactions with Dovato.

## Not to be used

ViiV recommends that the following drugs should not be used by people taking Dovato:

- for treatment of abnormal heart rhythms – dofetilide (Tikosyn)
- potassium channel blockers – fampridine (dalfampridine)

## Acid-reducing agents, laxatives, metal supplements and buffered medicines

Dovato should be taken at least 2 hours before or 6 hours after taking these medicines. Examples of acid-reducing agents include:

- Alka-Seltzer
- Gaviscon (tablets and syrup)
- Maalox (liquid and tablets)
- Milk of Magnesia
- Pepto-Bismol and Pepto-Bismol Children's
- Roloids
- Tums
- Zantac (ranitidine), Tagamet (cimetidine)

ViiV recommends that people who take calcium (for reasons other than stomach acid reduction) and/or iron supplements or multivitamins (which can contain calcium and iron) can take these supplements at the same time with Dovato so long as they take them with a meal. Alternatively, ViiV states that Dovato “should be taken two hours before or six hours after taking supplements containing calcium and/or iron.”

## Anti-seizure drugs

Drugs such as carbamazepine, oxcarbazepine, phenobarbital and phenytoin can reduce the level of dolutegravir in your body. However, some people must use one of these drugs to help reduce their risk for seizures. In such cases, ViiV recommends that “an additional 50 mg dose of [dolutegravir, sold as Tivicay] should be taken, separated by 12 hours from [when you take Dovato].”

## **Hypericin and hyperforin (see St. John's wort)**

### **Metformin**

The drug metformin is commonly used to help manage blood sugar levels. Dolutegravir, in Dovato, can raise levels of metformin in the body; this can cause loose stools or diarrhea. Your doctor may need to reduce your dose of metformin if you are also taking Dovato.

### **Rifampin**

The antibiotic rifampin can reduce levels of dolutegravir in the body. This can lead to the failure of Dovato and the development of HIV that is resistant to drugs in Dovato.

In some cases, such as treatment of TB (tuberculosis), it is medically necessary for doctors to prescribe rifampin. In such cases, ViiV recommends that an additional 50 mg of dolutegravir (Tivicay) should be taken separated by 12 hours from dosing of Dovato.

### **Sorbitol**

Sorbitol can reduce levels of 3TC in your body. ViiV states that “whenever possible, avoid chronic [use of] sorbitol-containing medicines with Dovato. Consider more frequent monitoring of HIV-1 viral load when chronic [use of sorbitol] cannot be avoided by people taking Dovato.”

## **St. John's wort (contains hypericin and hyperforin)**

In general, this herb and its extracts (hypericin, hyperforin) can interfere with many medicines. It may significantly reduce the amount of dolutegravir in your body. If you do take this herb (or its extracts) ViiV recommends that doctors consider prescribing an additional 50 mg dose of dolutegravir “separated by 12 hours from [when you take Dovato].”

## **Resistance and cross-resistance**

Over time, as new copies of HIV are made in the body, the virus changes its structure. These changes, called mutations, can cause HIV to resist the effects of anti-HIV drugs, which means those drugs will no longer work for you.

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, the level of dolutegravir and rilpivirine in the blood may fall too low. If this happens, the HIV in your body can become resistant to the medication. If you find you are having problems taking your medications as directed, speak to your doctor, nurse or pharmacist 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 options might be, at some point your doctor can have a small sample of your blood analyzed to test for resistance.

## **Dosage**

Dovato is supplied as white film-coated tablets. Each tablet contains 50 mg of dolutegravir and 300 mg of 3TC. Dovato is taken once daily with or without a meal.

If you forget to take a dose, ViiV recommends that “you take Dovato as soon as you remember. If your next dose is due within 4 hours, skip the dose that you missed and take the next one at the usual time. Don't take a double dose to make up for the missed dose.”

## **Availability**

Dovato is licensed in Canada. Your doctor or pharmacist can tell you more about the availability and coverage of dolutegravir in your region. CATIE's online module *Federal, Provincial and Territorial Drug Access Programs* also contains information about Canadian drug coverage.

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Production of this document has been made possible through a financial contribution from the Public Health Agency of Canada.

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