

DOVATO

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 DOVATO?

DOVATO contains two active ingredients: dolutegravir and lamivudine. DOVATO is used to treat HIV (human immunodeficiency virus) infection in adults and in children over the age of 12 years.

For more information, see Section [1. Why am I using DOVATO?](#) in the full CMI.

2. What should I know before I use DOVATO?

Do not use if you have ever had an allergic reaction to DOVATO 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 DOVATO?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DOVATO 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 DOVATO?

- Swallow the tablets whole with a full glass of water
- The usual dose of DOVATO in adults and in children over the age of 12 years weighing at least 40 kg is one tablet (50 mg Dolutegravir and 300 mg lamivudine) taken once a day

More instructions can be found in Section [4. How do I use DOVATO?](#) in the full CMI.

5. What should I know while using DOVATO?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using DOVATO• Stay in regular contact with your doctor. You will need regular blood tests
Things you should not do	<ul style="list-style-type: none">• Do not stop taking your medicine or lower the dosage without checking with your doctor• Do not take DOVATO to treat any other complaints unless your doctor tells you to• Do not give your medicine to anyone else, even if they have the same condition as you
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how DOVATO affects you• DOVATO can make you dizzy and have other side effects that make you less alert
Looking after your medicine	<ul style="list-style-type: none">• Store below 30°C• Store in original packaging

For more information, see Section [5. What should I know while using DOVATO?](#) in the full CMI.

6. Are there any side effects?

Side effects which have been reported include headache, feeling sick, diarrhoea, suicidal thoughts, depression, being sick, stomach pains, stomach discomfort, wind, lack of energy, generally feeling unwell, high temperature, dizziness, feeling drowsy, abnormal dreams, difficulty in sleeping, anxiety, hair loss, rash, itching, joint pain, muscle disorders and weight gain. Serious side effects include allergic reaction, lactic acidosis, inflammation of the pancreas, inflammation of the liver, liver failure, suicide attempt, breakdown of muscle tissue, tingling or numbness of the hands and feet and numbness, tingling or weakness of the arms and legs. 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.

DOVATO

Active ingredient(s): *dolutegravir/lamivudine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using DOVATO. **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 DOVATO.**

Where to find information in this leaflet:

- [1. Why am I using DOVATO?](#)
- [2. What should I know before I use DOVATO?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use DOVATO?](#)
- [5. What should I know while using DOVATO?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using DOVATO?

DOVATO contains two active ingredients: dolutegravir and lamivudine. Dolutegravir belongs to a group of anti-retroviral medicines called integrase inhibitors (INIs). Lamivudine belongs to a group of anti-retroviral medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs).

DOVATO is used to treat HIV (human immunodeficiency virus) infection in adults and in children over the age of 12 years.

DOVATO does not cure HIV infection, it reduces the amount of virus in your body and keeps it at a low level. DOVATO also increases the CD4 cell count in your blood.

CD4+ cells are a type of white blood cell that are important in helping your body to fight infection.

Because DOVATO does not cure HIV infection, you may still develop other infections and illnesses linked to HIV infection.

2. What should I know before I use DOVATO?

Warnings

Do not use DOVATO if:

- you are allergic to dolutegravir or lamivudine, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Some of the symptoms of an allergic reaction may include:
 - shortness of breath
 - wheezing or difficulty breathing
 - swelling of the face, lips, tongue or other parts of the body
 - rash, itching or hives on the skin

Check with your doctor if you:

- have any other medical conditions including:
 - liver disease, including hepatitis B or C (don't stop DOVATO without your doctor's advice, as your hepatitis may come back)
 - kidney disease
- take any medicines for any other condition

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?](#)

Pregnancy and breastfeeding

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

In babies and infants exposed to NRTIs during pregnancy or labour, small temporary increases in blood levels of a substance called lactate have been observed. Additionally, there have been very rare reports of diseases that affect the nervous system such as delayed development and seizures.

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

Where possible, women who are HIV-positive should not breast-feed because HIV infection can be passed on to the baby in breast milk.

If formula feeding is not possible, you should get advice from your doctor.

A small amount of the ingredients in DOVATO can also pass into your breast-milk.

Symptoms of infection and inflammation

People with advanced HIV infection (AIDS) have weak immune systems, and are more likely to develop serious infections (opportunistic infections). When they start treatment, the immune system becomes stronger, so the body starts to fight infections.

Symptoms of infection and inflammation may develop, caused by either:

- old, hidden infections flaring up again as the body fights them
- the immune system attacking healthy body tissue (autoimmune disorders)

The symptoms of autoimmune disorders may develop many months after you start taking medicine to treat your HIV infection.

Symptoms may include:

- muscle weakness and/or muscle pain
- joint pain or swelling
- weakness beginning in the hands and feet and moving up towards the trunk of the body

- palpitations or tremor
- hyperactivity (excessive restlessness and movement).

If you get any symptoms of infection while you're taking DOVATO, tell your doctor immediately. Don't take other medicines for the infection without your doctor's advice.

Use in children

DOVATO is not recommended for children under the age of 12 years as the dosage cannot be modified.

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.

Do not take DOVATO with these medicines:

- dofetilide or pilsicainide which are used to treat heart conditions
- fampridine which is used to treat multiple sclerosis
- emtricitabine, to treat HIV infection
- sorbitol-containing medicines (usually liquids) when used regularly

Some medicines may interfere with DOVATO and affect how it works. Tell your doctor if you are taking:

- metformin, to treat diabetes
- medicines called antacids, to treat indigestion and heartburn. Antacids can stop DOVATO being absorbed into your body and make it less effective. Do not take an antacid during the 6 hours before you take DOVATO, or for at least 2 hours after you take it. Other acid-lowering medicines like ranitidine and omeprazole can be taken at the same time as DOVATO
- calcium, magnesium and iron supplements. These medicines can stop DOVATO being absorbed into your body and make it less effective. Do not take a calcium, magnesium or iron supplement during the 6 hours before you take DOVATO, or for at least 2 hours after you take it. If you take food with your medicine, you can take a calcium, magnesium or iron supplement at the same time as DOVATO
- etravirine, efavirenz, nevirapine or tipranavir/ritonavir, to treat HIV infection
- rifampicin, to treat tuberculosis (TB) and other bacterial infections
- co-trimoxazole, an antibiotic used to treat Pneumocystis jiroveci pneumonia (often referred to as PJP or PCP) or toxoplasmosis
- phenytoin and phenobarbital, to treat epilepsy
- carbamazepine, to treat epilepsy and bipolar disorder
- St. John's Wort (Hypericum perforatum), a herbal remedy to treat depression

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DOVATO.

4. How do I use DOVATO?

How much to take

- follow the instructions provided and use DOVATO until your doctor tells you to stop
- the usual dose of DOVATO in adults and in children over the age of 12 years weighing at least 40 kg is one tablet (50 mg dolutegravir and 300 mg lamivudine) taken once a day
- if you weigh less than 40kg, you cannot take DOVATO, because the dose of each component of this medicine cannot be adjusted to your weight. Your doctor might prescribe the components separately for you

When to take DOVATO

- DOVATO should be taken at the same time each day to have the best effect. It will also help you remember when to take it
- it does not matter if you take this medicine before or after food
- swallow the tablets whole with a full glass of water

If you forget to use DOVATO

DOVATO 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. But if your next dose is due within 4 hours, skip the dose you missed and take the next one at the usual time. Then continue your treatment as before.

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

If you use too much DOVATO

If you think that you have used too much DOVATO, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **0800 POISON** or **0800 764 766**), 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 DOVATO?

Things you should do

Stay in regular contact with your doctor.

You will need regular blood tests.

For as long as you're taking DOVATO, your doctor will arrange regular blood tests to check for side effects.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

Call your doctor straight away if you:

- become pregnant while taking this medicine

Remind any doctor, dentist or pharmacist you visit that you are using DOVATO.

Things you should not do

- do not take DOVATO to treat any other complaints unless your doctor tells you to
- do not give your medicine to anyone else, even if they have the same condition as you
- do not stop taking your medicine or lower the dosage without checking with your doctor

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DOVATO affects you.

DOVATO can make you dizzy and have other side effects that make you less alert.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- store below 30°C
- store in original packaging

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.

When you're being treated for HIV, it can be hard to tell whether a symptom is a side effect of DOVATO or other medicines you are taking, or an effect of the HIV disease itself. So it is very important to talk to your doctor about any changes in your health.

Some side effects may only be seen in your blood tests, and may not appear immediately after you start taking DOVATO. If you get any of these effects, and if they are severe, your doctor may advise you to stop taking DOVATO.

Less serious side effects

Less serious side effects	What to do
<p>Gastrointestinal disorders:</p> <ul style="list-style-type: none"> • feeling sick (nausea) • diarrhoea • stomach pains (abdominal pain) • stomach (abdominal) discomfort • wind (flatulence) • being sick (vomiting) <p>Nervous system disorders:</p> <ul style="list-style-type: none"> • headache • dizziness • abnormal dreams • difficulty in sleeping (insomnia) <p>Musculoskeletal and connective tissue disorders:</p> <ul style="list-style-type: none"> • joint pain (arthralgia) • muscle disorders • muscle pain (myalgia) <p>Skin and subcutaneous tissue disorders:</p> <ul style="list-style-type: none"> • hair loss (alopecia) • rash • itching (pruritus) <p>General disorders and administration side conditions:</p> <ul style="list-style-type: none"> • lack of energy (fatigue) • generally feeling unwell (malaise) • high temperature (fever) • feeling drowsy <p>Psychiatric disorders:</p> <ul style="list-style-type: none"> • suicidal thoughts (mainly in patients who have had depression or mental health problems before) • depression • anxiety <p>Metabolism and nutrition disorders:</p> <ul style="list-style-type: none"> • weight gain 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Gastrointestinal disorders:</p> <ul style="list-style-type: none"> • inflammation of the pancreas (pancreatitis) <p>Hepatobiliary disorders:</p> <ul style="list-style-type: none"> • inflammation of the liver (hepatitis) 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of</p>

- liver failure (signs may include yellowing of the skin and the whites of the eyes or unusually dark urine)

Psychiatric disorders:

- suicide attempt (mainly in patients who have had depression or mental health problems before)

Musculoskeletal and connective tissue disorders:

- breakdown of muscle tissue (rhabdomyolysis)

Nervous system disorders:

- tingling or numbness of the hands and feet (paraesthesiae)
- numbness, tingling or weakness of the arms and legs (peripheral neuropathy)

Immune system disorders and allergic reactions:

- skin rash
- a high temperature (fever)
- lack of energy (fatigue)
- swelling, sometimes of the face or mouth (angioedema), causing difficulty in breathing
- muscle or joint aches

Metabolism and nutrition disorders:

- lactic acidosis (together with an enlarged liver), is caused by a build-up of lactic acid in the body. It is rare; if it happens, it usually develops after a few months of treatment. It can be life-threatening, causing failure of internal organs

Lactic acidosis is more likely to develop in people who have liver disease, especially in women. Signs of lactic acidosis include:

- deep, rapid, difficult breathing
- drowsiness
- numbness or weakness in the limbs
- feeling sick (nausea)
- being sick (vomiting)
- stomach pain

Blood related:

- Anaemia. Signs and symptoms include:
 - Fatigue

these serious side effects.

Your doctor may decide to carry out tests on your liver, kidneys or blood, and may tell you to stop taking DOVATO.

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|---|--|
| <ul style="list-style-type: none"> ○ Weakness ○ Shortness of breath ○ Heart palpitations ○ Headache | |
|---|--|

Additional side effects which will only be picked up on a blood test include:

- signs of a condition where red blood cells do not form properly (sideroblastic anaemia).
- a low red blood cell count (anaemia) or low white blood cell count (neutropenia)
- a decrease in the number of cells involved in blood clotting (thrombocytopenia)
- an increase in the level of liver enzymes
- increase in bilirubin (a substance produced by the liver) in the blood
- an increase in the level of enzymes produced in the muscles (creatine phosphokinase)
- an increase in a kidney function blood test result (creatinine)
- an increase in lactic acid in the blood which on rare occasions can lead to lactic acidosis (refer to serious side effects)
- increase in an enzyme called amylase
- failure of the bone marrow to produce new red blood cells (pure red cell aplasia)

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 via <https://pophealth.my.site.com/carmreportnz/s/>

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 DOVATO contains

Active ingredient (main ingredient)	dolutegravir sodium lamivudine
Other ingredients (inactive ingredients)	mannitol magnesium stearate microcrystalline cellulose povidone sodium starch glycollate Type A sodium stearyl fumarate hypromellose macrogol 400

	titanium dioxide
Potential allergens	mannitol

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

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

What DOVATO looks like

DOVATO is an oval, biconvex, white, film-coated tablet, debossed with "SV 137" on one face.

They are supplied in a white bottle which contains 30 tablets. (TT50-10811).

Who distributes DOVATO

GlaxoSmithKline NZ Ltd
Private Bag 106600
Downtown
Auckland 1143
New Zealand

Phone: (09) 367 2900

Facsimile: (09) 367 2910

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