

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 taking DOVATO?

DOVATO contains the active ingredients dolutegravir and lamivudine. DOVATO is used to treat HIV infection.

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

2. What should I know before I take DOVATO?

Do not use if you have ever had an allergic reaction to dolutegravir, lamivudine or any of the ingredients listed at the end of the CMI.

Do not take DOVATO if you are taking dofetilide or pilsicainide (used to treat heart conditions) or fampridine (for multiple sclerosis).

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 take 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 take DOVATO?

- The usual dosage of DOVATO is one tablet once a day
- Swallow the tablet whole with a glass of water

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

5. What should I know while taking DOVATO?

| | |
|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking DOVATO.• For as long as you are taking DOVATO, your doctor will arrange for you to have regular blood tests to check for side effects. |
| Things you should not do | <ul style="list-style-type: none">• Do not stop using this medicine suddenly or change the dose without talking to your doctor.• Do not take this medicine to treat any other complaints.• Do not give this medicine to children under the age of 12. |
| 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 may cause dizziness and tiredness in some people. |
| Looking after your medicine | <ul style="list-style-type: none">• Store DOVATO below 30°C in the pack.• Keep this medicine in the pack until it is time to take it. |

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

6. Are there any side effects?

Side effects that have been reported include headache, feeling sick (nausea) and vomiting, abdominal pain or discomfort, diarrhoea, increased wind (flatulence), fatigue, tiredness, lack of energy, a general feeling of being unwell, fever, dizziness, loss of hair, rash and itching, joint pain, muscle pain, weight gain, abnormal dreams, difficulty sleeping, depression, anxiety, having suicidal thoughts (mainly in patients who have had depression or mental health problems previously).

Allergic reaction has also been reported. Signs include swelling of the lips, tongue, wheezing or difficulty breathing, rash, hives on the skin. If this occurs seek medical attention immediately.

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

1. Why am I taking DOVATO?

DOVATO contains the active ingredients dolutegravir and lamivudine.

DOVATO belongs to a group of medicines known as antiretrovirals.

DOVATO is used to treat HIV infection in adults and children over the age of 12.

DOVATO does not cure AIDS or HIV infection however it slows down production of HIV in the body. In this way it stops ongoing damage to the body's immune system which fights infection.

You can still pass on HIV when taking this medicine through sexual activity or through passing on blood or bodily secretions which carry the HIV virus, although the risk is lowered by taking antiretroviral therapy.

You should use proper precautions to prevent this from occurring. Discuss with your doctor the precautions needed to avoid infecting other people.

While taking DOVATO and/or any other therapy for HIV, you may continue to develop other infections and other complications of HIV infection. You should keep in regular contact with your doctor.

2. What should I know before I take DOVATO?

Warnings

Do not use DOVATO if:

- you are allergic to dolutegravir, 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.

- you are taking dofetilide or pilsicainide (medicines used to treat heart conditions)
- you are taking fampridine (a medicine used to treat multiple sclerosis)

Check with your doctor if you:

- have any other medical conditions

- have or have had any liver disease, including hepatitis B or C
- have or have had kidney disease

If you have a long-standing viral infection of your liver (hepatitis B) it may flare up. 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 stop taking DOVATO your doctor is likely to arrange tests from time to time to check how well your liver is working and to measure virus levels.

- 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

Talk to your doctor if you are pregnant or intend to become pregnant.

It is important to use a reliable method of contraception whilst taking DOVATO to prevent pregnancy.

Taking dolutegravir (one of the components of DOVATO) at the time of becoming pregnant or during the first 12 weeks of pregnancy may increase the risk of a type of birth defect known as a neural tube defect, such as spina bifida (malformed spinal cord).

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 a 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 as HIV infection can be passed from the mother to the child in the breast milk. Dolutegravir is known to pass into the breastmilk in small amounts. Talk to your doctor if you are unable to formula feed.

Your doctor can discuss with you the benefits and risks of taking DOVATO whilst pregnant or breast-feeding.

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 and so the body starts to fight infections.

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

- old, hidden infections flaring up at 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 medications to treat your HIV infection.

Symptoms may include:

- muscle weakness and/or muscle pain
- joint pain or swelling
- weakness beginning in the hands or feet and moving towards the trunk of the body
- palpitations or tremor
- hyperactivity (excessive restlessness and movement)

If you get symptoms of infection or if you notice any of the symptoms above, tell your doctor immediately. Do not take other medicines for the infection without your doctor's advice.

Children and adolescents

DOVATO is not recommended for use in children under 12 years of age. DOVATO is a fixed dose combination tablet and as such it cannot be adjusted according to the size and weight of the patient.

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.

Some medicines may interfere with DOVATO and affect how it works.

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

These medicines should not be taken with DOVATO:

- emtricitabine - a medicine used to treat HIV infection
- sorbitol-containing medicines (usually come in liquid form) when used regularly

Tell your doctor or pharmacist if you are taking any of the medicines below:

- metformin, used to treat diabetes
- medicines called antacids, to treat indigestion and heartburn.

Do not take an antacid during the 6 hours before you take DOVATO, or for at least 2 hours after you take it.

- calcium, magnesium and iron supplements.

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, medicines used to treat HIV infection
- rifampicin, a medicine used 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, medicines that treat epilepsy
- carbamazepine, a medicine used 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 take DOVATO?

How much to take

- The usual dosage of DOVATO in adults and children over the age of 12 and weighing at least 40 kg is one tablet once a day
- Follow the instructions provided and use DOVATO until your doctor tells you to stop.

When to take DOVATO

- Your doctor or pharmacist will tell you when to take DOVATO each day.

How to take DOVATO

- Swallow the tablet whole with a glass of water
- Do not halve the tablet
- You can take DOVATO with or without food
- If you are taking an antacid medicine it can stop DOVATO from 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.
- If you are taking calcium or iron supplements they can also stop DOVATO from being absorbed into your body and make it less effective. Do not take your calcium or iron supplement during the 6 hours before you take DOVATO or for at least 2 hours after you take it. If you take DOVATO with food then you can also take your calcium or iron supplement at the same time as you take DOVATO.

If you forget to take DOVATO

DOVATO should be used regularly at the same time each day.

If your next dose is due within the next 4 hours, skip the dose you missed and take the next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

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

If you take too much DOVATO

If you think that you have taken too much DOVATO, 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 taking DOVATO?

Things you should do

Ensure you have blood tests when you are meant to. It is important that your doctor monitors your health.

Tell your doctor straight away if you:

- become pregnant or intend to become pregnant
- have not taken DOVATO as intended

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

Things you should not do

- Do not stop using this medicine suddenly or change the dose.
- 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 tells you to.
- Do not give this medicine to children under the age of 12.

Stay in regular contact with your doctor

DOVATO helps to control your condition, but it is not a cure for HIV infection. You need to keep taking it everyday to stop your illness from getting worse. Because DOVATO does not cure HIV infections, you may still develop other infections and illnesses linked to HIV.

Driving or using machines

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

DOVATO may cause dizziness and tiredness in some people.

Looking after your medicine

Follow the instructions on the pack on how to take care of your medicine properly.

Store it in a cool dry place (below 30°C) 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.

Within the first few weeks of treatment with anti-HIV medicines, some people, particularly those that have been HIV positive for some time, may develop inflammatory reactions (e.g. pain, redness, swelling, high temperature) which may resemble an infection and may be severe. It is thought that these reactions are caused by a recovery in the

body's ability to fight infections, previously suppressed by HIV.

If you become concerned about any new symptoms, or any changes in your health after starting HIV treatment, discuss with your doctor immediately.

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 |
|--|---|
| <ul style="list-style-type: none"> • headache • feeling sick (nausea), vomiting • abdominal pain or discomfort • diarrhoea • increased wind (flatulence) • fatigue, tiredness, lack of energy • a general feeling of being unwell (malaise) • fever • dizziness • loss of hair (alopecia) • rash • itching (pruritus) • joint pain (arthralgia), muscle disorders, muscle pain (myalgia) • weight gain • abnormal dreams • difficulty sleeping (insomnia) • depression, anxiety • having suicidal thoughts (mainly in patients who have had depression or mental health problems previously) | <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 |
|--|--|
| <ul style="list-style-type: none"> • swelling of the lips, tongue, wheezing or difficulty breathing, rash, hives on the skin. These are all signs of an allergic reaction. • lactic acidosis <p>If you are taking medication for HIV and become unwell with fast breathing, drowsiness or numbness or weakness in the limbs, stop taking DOVATO and talk to your doctor immediately. The fast breathing is due to high acid levels in the blood. Your liver may not be working properly and gets big and fatty and can be life threatening. This illness occurs more often in women than men.</p> <ul style="list-style-type: none"> • hepatitis (inflammation of the liver) • increase in liver enzymes <p>These will be picked up on a blood test.</p> <p>Signs of liver failure including yellowing of the skin and whites of the eyes, unusually dark urine.</p> | <p>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.</p> |

| Serious side effects | What to do |
|--|------------|
| <ul style="list-style-type: none"> reduced red blood cell count (anaemia) reduced white blood cell count (neutropenia) reduced platelet count (thrombocytopenia) <p>Your doctor will ask you to have blood tests to monitor your levels of blood cells.</p> | |
| <ul style="list-style-type: none"> signs of an inflamed pancreas (pancreatitis) such as severe stomach pain or cramps, nausea, vomiting breakdown of muscle tissue (rhabdomyolysis) tingling or numbness of the hands and feet (paraesthesiae) tingling or numbness of the arms and legs (peripheral neuropathy) | |

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

- increase in the enzyme amylase
- failure of the bone marrow to produce new red blood cells (pure red cell aplasia)
- increase in bilirubin (a substance produced by the liver)
- increase in the level of enzymes produced in the muscles (creatinine phosphokinase)

increase in creatinine (a marker of kidney function)

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 DOVATO contains

| | |
|---|--|
| Active ingredient (main ingredient) | dolutegravir lamivudine |
| Other ingredients (inactive ingredients) | hypromellose macrogol 400 magnesium stearate mannitol |

| | |
|----------------------------|---|
| | microcrystalline cellulose povidone sodium starch glycolate type A sodium stearyl fumarate titanium dioxide |
| Potential allergens | mannitol |

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

What DOVATO looks like

DOVATO tablets are oval, biconvex, white, film-coated tablets, debossed with "SV 137" on one side.

DOVATO is supplied in bottles of 30 tablets (AUST R 309378).

Who distributes DOVATO

ViiV Healthcare Pty Ltd
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Australia

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