
PATIENT INFORMATION LEAFLET

DOVATO 50 mg/300 mg Film-coated tablets

dolutegravir/lamivudine

Read all of this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again. If you have any questions, ask your doctor or pharmacist.

This medicine has been prescribed for you personally. Don't pass it on to other people - it may harm them even if their symptoms seem to be the same as yours.

In this leaflet

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- 2. Before you take DOVATO**
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1. What DOVATO is and what it is used for

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

DOVATO contains two active ingredients that are used to treat HIV infection: 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 does not cure HIV infection; it reduces the amount of virus in your body, and keeps it at a low level. It also increases the CD4 cell count in your blood. CD4 cells are a type of white blood cells that are important in helping your body to fight infection.

Not everyone responds to treatment with DOVATO in the same way. Your doctor will monitor the effectiveness of your treatment.

2. Before you take DOVATO

Don't take DOVATO

- if you are **allergic (hypersensitive) to dolutegravir or lamivudine**, or any other ingredients of DOVATO (listed in **Section 6**)
 - if you're taking another medicine called **dofetilide** or **pilsicanide** (to treat heart conditions), or **fampridine** (also known as dalfampridine; used in multiple sclerosis).
- ➔ If you think either of these applies to you, **don't take DOVATO** until you have checked with your doctor.

Take special care with DOVATO

Before you take DOVATO your doctor needs to know:

- if you have **liver disease** or have ever had **liver disease**, including hepatitis B or C
- if you have ever had **kidney disease**.

Talk to your doctor if either of these applies to you. You may need extra check-ups, including blood tests, while you're taking your medication. **See Section 4 for more information.**

Conditions you need to look out for

DOVATO can cause serious side effects. You must look out for certain symptoms while you are taking DOVATO, to reduce the risk of any problems.

Allergic reactions

Contact your doctor promptly if you develop a rash. Some people taking DOVATO have had allergic reactions. See '*Allergic reactions*' in **Section 4**.

Symptoms of infection and inflammation

See '*Conditions you need to look out for*' in **Section 4**.

Lactic acidosis

A condition that is caused by build-up of lactic acid in the body. It is more likely to develop in people who have liver disease, especially in women.

See '*Lactic acidosis*' in **Section 4**.

Other medicines and DOVATO

Tell your doctor or pharmacist if you're taking any other medicines, if you've taken any recently, or if you start taking new ones. DOVATO can also affect how some other

medicines work. This includes herbal medicines and other medicines bought without a prescription.

Don't take DOVATO with dofetilide or pilsicainide, medicines used to treat **heart conditions**, or with **fampridine** (also known as dalfampridine), used in multiple sclerosis)

These medicines should not be used with DOVATO:

- emtricitabine, to treat **HIV infection**
- sorbitol-containing medicines (usually liquids) used regularly.

➔ **Tell your doctor** if you're being treated with any of these.

Tell your doctor if you are taking any of the medicines *in the following list*:

- metformin, 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 (*see also Section 3*).
- calcium and iron supplements. **Do not take a 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 food with your medicine you can take a calcium or iron supplement at the same time as DOVATO (*see also Section 3*).
- etravirine, efavirenz, nevirapine or tipranavir/ritonavir, to treat **HIV infection**
- rifampicin, to treat tuberculosis (TB) and other **bacterial infections**
- trimethoprim-sulphamethoxazole (also known as co-trimoxazole), (an **antibiotic** used to treat *Pneumocystis jiroveci* pneumonia (often referred to as 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**

➔ **Tell your doctor or pharmacist** if you are taking any of these. Your doctor may decide to adjust your dose or that you need extra checkups.

Pregnancy

If you are **pregnant**, or **think you could be**, or if you are **planning to become pregnant**, **don't take DOVATO** without checking with your doctor. **Your doctor** will consider the benefit to you against the risk to your baby of taking DOVATO while you're pregnant.

If you **could get pregnant** while receiving DOVATO, you need to use a reliable method of **contraception**, to prevent pregnancy.

Taking dolutegravir (one of the components of DOVATO) at the time of becoming pregnant, or during the first twelve weeks of pregnancy, may increase the risk of a type of birth defect, called 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.

Breast-feeding

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.

- **Talk to your doctor immediately** if you're breast-feeding, or thinking about breast-feeding.

Driving and using machines

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

- **Don't drive or use machines** unless you are sure you're not affected.

While you're taking DOVATO

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. There's more information about these side effects in **Section 4** of this leaflet.

Stay in regular contact with your doctor

DOVATO helps to control your condition. You need to keep taking it every day to stop your illness from getting worse. You may still develop other infections and illnesses linked to HIV infection.

- **Keep in touch with your doctor, and don't stop taking DOVATO** without your doctor's advice.

Protect other people

HIV infection is spread by sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles). You can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor the precautions needed to avoid infecting other people.

Children

This medicine is not for use in children under 12 years of age, because it has not been studied in these patients.

3. How to take DOVATO

Always take DOVATO exactly as your doctor has told you to. Check with your doctor or pharmacist if you're not sure.

How much to take

The usual dose of DOVATO in adults and in children over the age of 12 years weighing at least 40 kg is one combined tablet (50 mg dolutegravir and 300 mg lamivudine) taken once a day.

If you weigh less than 40 kg, 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.

How to take

Swallow the tablet with some liquid.

DOVATO can be taken with or without food.

Antacid medicines

Antacids, to treat **indigestion** and **heartburn**, 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. Talk to your doctor or pharmacist for further advice on taking acid-lowering medicines with DOVATO.

Calcium or iron supplements

Calcium or iron supplements can stop DOVATO being absorbed into your body and make it less effective.

Do not take a 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 food with DOVATO, then you can take calcium and iron supplements at the same time as DOVATO.

If you forget to take DOVATO

If you miss a dose, 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.

Don't take a double dose to make up for a missed dose. Just take it as soon as you remember.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much DOVATO

If you take too many tablets of DOVATO, **contact your doctor or pharmacist for advice**. If possible, show them the DOVATO pack.

Don't stop DOVATO without advice

Take DOVATO for as long as your doctor recommends. Don't stop unless your doctor advises you to.

If you have hepatitis B infection, don't stop DOVATO without your doctor's advice, as your hepatitis may come back.

4. Possible side effects

Like all medicines, DOVATO can cause side effects, although not everybody gets them.

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.

As well as the effects listed below for DOVATO, other conditions can develop during therapy for HIV.

- **It is important to read the information** in '*Conditions you need to look out for*', later in this section.

Allergic reactions

These are uncommon in people taking DOVATO. If you get any of the following symptoms:

- 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.

- **Contact your doctor as soon as possible**. Your doctor may decide to carry out tests on your liver, kidneys or blood, and may tell you to stop taking DOVATO.

Lactic acidosis is a rare but serious side effect

Some people taking DOVATO, or other medicines like it (NRTIs), develop a condition called lactic acidosis, together with an enlarged liver.

Lactic acidosis 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.**

During your treatment, your doctor will monitor you for signs of lactic acidosis. If you have any of the symptoms listed above or any other symptoms that worry you:

→ **See your doctor as soon as possible.**

As well as the conditions listed above, other side effects can develop during combination therapy for HIV.

Very common side effects

These may affect **more than 1 in 10** people:

- headache
- diarrhoea
- feeling sick (*nausea*).

Common side effects

These may affect **up to 1 in 10** people:

- suicidal thoughts (mainly in patients who have had depression or mental health problems before)
- depression (feelings of deep sadness and unworthiness)
- being sick (*vomiting*)
- stomach pains (*abdominal pain*)
- stomach (*abdominal*) discomfort
- wind (*flatulence*)
- lack of energy (*fatigue*)
- generally feeling unwell (*malaise*)
- high temperature (*fever*)

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- dizziness
 - feeling drowsy
 - abnormal dreams
 - difficulty in sleeping (*insomnia*)
 - anxiety
 - hair loss (*alopecia*)
 - rash
 - itching (*pruritis*)
 - joint pain (*arthralgia*)
 - muscle disorders.

Common side effects that may show up in your blood tests:

- an increase in *lactic acid* in the blood, which on rare occasions can lead to lactic acidosis.

Uncommon side effects

These may affect **up to 1 in 100 people**:

- allergic reaction (See '*allergic reactions*' earlier in this section)
- inflammation of the liver (*hepatitis*)
- Suicide attempt (mainly in patients who have had depression or mental health problems before)
- muscle pain (*myalgia*)
- weight gain.

Uncommon side effects that may show up in blood tests are:

- 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.

Rare side effects

These may affect **up to 1 in 1000 people**:

- lactic acidosis (see '*lactic acidosis is a rare but serious side effect*' earlier in this section)
- liver failure (signs may include yellowing of the skin and the whites of the eyes or unusually dark urine)
- inflammation of the pancreas (*pancreatitis*)
- breakdown of muscle tissue (*rhabdomyolysis*).

Rare side effects that may show up in blood tests are:

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- increase in an enzyme called amylase.

Very rare side effects

These may affect **up to 1 in 10,000** people:

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

Very rare side effects that may show up in blood tests are:

- failure of the bone marrow to produce new red blood cells (*pure red cell aplasia*).

If you get side effects

→ **Tell your doctor or pharmacist** if any of the side effects gets **severe or troublesome**, or if you notice any side effects not listed in this leaflet.

Other side effects that may show up in blood tests

Other side effects have occurred in some people but their exact frequency is unknown:

- 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).

Tell your doctor or pharmacist if any of the side effects listed becomes **severe or troublesome**, or if you notice any side effects not listed in this leaflet.

Conditions you need to look out for

Some other conditions may develop during HIV treatment.

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**

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- **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.

Joint pain, stiffness and bone problems

Some people taking combination therapy for HIV develop a condition called *osteonecrosis*. With this condition, parts of the bone tissue are permanently damaged because of reduced blood supply to the bone.

People may be more likely to get this condition:

- if they have been taking combination therapy for a long time
- if they are also taking anti-inflammatory medicines called corticosteroids
- if they drink alcohol
- if their immune systems are very weak
- if they are overweight.

Signs of osteonecrosis include:

- stiffness in the joints
- aches and pains in the joints (especially in the hip, knee or shoulder)
- difficulty moving.

If you notice any of these symptoms:

➔ **Tell your doctor.**

5. How to store DOVATO

Store up to 30°C.

Keep this medicine out of the sight and reach of children.

Do not use DOVATO after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Don't throw away any medicines in wastewater or household waste. Ask your pharmacist how to throw away medicines no longer required. This will help to protect the environment.

6. Further information

What DOVATO contains

The active substances are dolutegravir (as dolutegravir sodium) and lamivudine.

Each film-coated tablet contains 50 mg dolutegravir (present as dolutegravir sodium), and 300 mg lamivudine.

Other Ingredients are:

Tablet core: Microcrystalline cellulose, Sodium starch glycolate, Magnesium Stearate, Mannitol (E421), Povidone (K29/32), Sodium stearyl fumarate

Tablet coating: Hypromellose (E464), Macrogol, Titanium dioxide (E171)

What DOVATO looks like and contents of the pack

DOVATO tablets are available in opaque, white high density polyethylene (HDPE) bottles with polypropylene child-resistant closures.

Each pack consists of one bottle containing 30 film-coated tablets.

Product Registrant

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