

SMPC
Dolutegravir 50mg Tablets¹
Dolutegravir

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 further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your healthcare provider.

In this leaflet:

1. What Dolutegravir 50mg Tablet is and what it is used for
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1. What Dolutegravir 50mg tablet is and what it is used for

Dolutegravir Tablets 50mg contains the active ingredient dolutegravir. Dolutegravir belongs to a group of anti-retroviral medicines called integrase inhibitors.

Dolutegravir Tablets 50mg is used to treat HIV (human immunodeficiency virus) infection in adults and young people who weigh at least 40 kg. It is always used in combination with other anti-retroviral medicines (combination therapy).

Dolutegravir Tablets 50mg does not cure HIV infection; it reduces the amount of virus in your body and keeps it at a low level. Reducing the amount of virus helps to increase number of white blood cells, called CD4 cells, that are important for fighting infection.

Dolutegravir Tablets 50mg does not work equally well in everybody. Your health care provider will check how well your treatment is working.

To control your HIV infection, and to stop your illness from getting worse, you must take all your HIV medicines regularly, unless your health care provider tells you to stop taking any.

2. Before you take Dolutegravir tablets 50mg

Do not take Dolutegravir Tablets 50mg if you are:

- if you are allergic to dolutegravir or any of the other ingredients of this medicine (listed in section 6)
- if you are taking another medicine called dofetilide (to treat heart conditions).
- if you think any of these apply to you, tell your health care provider.

Take special care with Dolutegravir 50mg Tablet

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Throughout a WHOPAR the proprietary name is given as an example only.

Warnings and precautions

Look out for important symptoms

Some people taking medicines for HIV infection develop other conditions, which can be serious. These include

- infections and inflammation
- joint pain, stiffness and bone problems

You need to know about important signs and symptoms to look out for while you're taking Dolutegravir (as sodium) 50mg Tablets.

Read the information, 'Other possible side effects' in Section 4 of this leaflet.

Protect other people

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

Children

Dolutegravir Tablets 50mg is suitable only for children and young people who weigh at least 40 kg. Other medicines that contain a smaller amount of dolutegravir are needed for patients who weigh less than 40 kg. There is not yet enough information to recommend the use of dolutegravir in children under 6 years or weighing less than 15 kg.

Taking other medicines

Please tell your health care provider if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

You **must not** take Dolutegravir Tablets 50mg with dofetilide, which is used to treat heart conditions.

Some medicines can affect how Dolutegravir Tablets 50mg works or increase side effects. Dolutegravir Tablets 50mg can also affect how some other medicines work.

Tell your health care provider if you are taking any of the following:

- metformin, to treat diabetes
- antacids, to treat indigestion and heartburn. Do not take an antacid during the 6 hours before you take Dolutegravir 50mg Tablets, or for at least 2 hours after you take it
- calcium supplements, iron supplements and multivitamins. Do not take a calcium supplement, iron supplement or multivitamin during the 6 hours before you take Dolutegravir (as sodium) 50mg Tablets, or for at least 2 hours after you take it

- etravirine, efavirenz, fosamprenavir/ritonavir, nevirapine or tipranavir/ritonavir, to treat HIV infection
- rifampicin, to treat tuberculosis and other bacterial infections
- phenytoin and phenobarbital, to treat epilepsy
- oxcarbazepine and carbamazepine, to treat epilepsy or bipolar disorder
- St John's wort (*Hypericum perforatum*), a herbal remedy used for treating depression
- If you are taking any of these, your health care provider may adjust your dose or arrange extra check-ups.

Taking Dolutegravir 50 mg Tablet with food and drink

Dolutegravir Tablets 50mg may be taken with or without food.

Pregnancy and Breast-feeding

Pregnancy

If you are pregnant, if you become pregnant, or if you are planning to have a baby talk to your health care provider about the risks and benefits of taking Dolutegravir 50mg Tablets. Your health care provider will review your treatment.

Taking Dolutegravir Tablets 50mg 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).

If you could get pregnant while receiving Dolutegravir Tablets 50mg and you are not planning to become pregnant, it is recommended that,

- you undergo pregnancy testing
- you use effective contraception to prevent pregnancy

Do not discontinue Dolutegravir Tablets 50mg without consulting your health care provider, as this may harm you and your unborn child.

Breast-feeding

If you wish to breast-feed your baby, you should discuss the risks and benefits with your health care provider.

Driving and using machines

Dolutegravir Tablets 50mg can make you dizzy and have other side effects that make you less alert. Do not drive or operate machinery until you are sure that you do not have side effects that affect driving or using machines.

Important information about some of the ingredients of Dolutegravir (as sodium) 50mg Tablets

Dolutegravir Tablets 50mg contains mannitol which may have a mild laxative effect.

3. How to take dolutegravir (as sodium) 50 mg tablets

Always take Dolutegravir Tablets 50mg exactly as your health care provider has told you. Do not stop taking it without checking with your health care provider. Check with the health care provider if you are not sure.

The usual dose is one tablet (50 mg) once a day.

In the following cases your health care provider will decide on a higher dose of one tablet twice a day:

- if you are taking certain other medicines at the same time
- if your HIV infection is resistant to medicines similar to Dolutegravir (as sodium) 50mg Tablets.

You can take Dolutegravir Tablets 50mg with food or between meals but if you need to take the medicine twice a day, your health care provider may advise you take Dolutegravir Tablets 50mg with food.

Antacids, calcium supplements, iron supplements, multivitamins

Ask your health care provider for advice if you are taking:

- an antacid (a medicine used for treating indigestion and heartburn)
- calcium supplements
- iron supplements
- multivitamins

Take these medicines at least 6 hours before you take Dolutegravir Tablets 50mg or take Dolutegravir Tablets 50mg at least 2 hours after taking an antacid, calcium or iron supplement, or multivitamins.

Children and adolescents

The dose of Dolutegravir Tablets 50mg in children and adolescents weighing at least 40 kg is one tablet (50 mg), once a day.

Children and adolescents whose HIV infection is resistant to medicines similar to Dolutegravir Tablets 50mg should not take Dolutegravir 50mg Tablets.

Dolutegravir Tablets 50mg is not suitable for children weighing less than 40 kg and other medicines containing dolutegravir may be more suitable.

If you take more Dolutegravir Tablets 50mg than you should

If you take too many tablets of Dolutegravir 50mg Tablets, contact your health care provider for advice. If possible, show them the Dolutegravir Tablets 50mg pack.

If you forget to take Dolutegravir 50mg Tablets

If you miss a dose of Dolutegravir 50mg Tablets, 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. You must not take a double dose to make up for a missed dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects but not everybody gets them.

Talk to your health care provider if there is any worsening of your health. The changes could be caused by the medicine or the condition getting worse.

Allergic reactions

See a health care provider straightaway if you get an allergic reaction because the health care provider may decide that you should stop taking Dolutegravir 50mg Tablets. The signs of allergic reactions are:

- skin rash fever
- tiredness
- swelling under the skin which can involve the face or mouth and breathing difficulty
- muscle and joint ache

Very common side effects (which affect more than 1 in 10 people)

headache
diarrhoea
feeling sick (nausea)

Common side effects (which may affect up to 1 in 10 people)

rash, itching (pruritus)
being sick (vomiting), abdominal (belly) pain and discomfort, wind (flatulence)
insomnia, abnormal dreams, depression
dizziness, tiredness
blood tests showing changes in liver function
blood tests with increased muscle enzymes (creatine kinase) indicating muscle damage

Uncommon side effects (which may affect up to 1 in 100 people)

inflammation of the liver (hepatitis)
suicidal thoughts and behaviours (particularly in patients who have had depression or mental health problems before)
joint and muscle pain

Other possible side effects

People taking medicines for HIV may get other side effects described below.

Infection and inflammation

People with advanced HIV infection (AIDS) have weak immune systems and they are more likely to develop serious infections (opportunistic infections). Such infections may have been 'silent' before starting HIV treatment. After starting treatment, the immune system becomes stronger, and may attack the infections, which can cause symptoms of infection or inflammation. Symptoms usually include fever, headache, stomach ache, and breathing difficulty.

In rare cases, as the immune system becomes stronger, it can also attack 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 palpitations (rapid or irregular heartbeat), tremor, excessive restlessness and movement, weakness beginning in the hands and feet and moving up towards the trunk of the body.

Speak to your health care provider **immediately** if you get any symptoms of infection and inflammation. Do not take other medicines for the infection without checking with your health care provider.

Joint pain, stiffness and bone problems

Some people taking combination therapy for HIV develop a condition called osteonecrosis. This condition is caused by damage to parts of the bone tissue because of reduced blood supply to the bone. People taking combination therapy for a long time may be more likely to get this condition if they are also taking medicines called corticosteroids, drink alcohol, have a weak immune system, are very weak or are overweight.

Signs of osteonecrosis include joint stiffness, aches and pains in the joints (especially in the hip, knee or shoulder), difficulty moving.

Speak to your health care provider if you notice any of these effects.

Reporting of side effects

If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. If available, you can also report side effects directly through the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

5. How to store Dolutegravir 50mg Tablets

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

Do not store above 30°C.

Do not use this medicine after the expiry date stated on the pack.

Do not use this medicine if you notice visible signs of deterioration.

Do not throw away any medicines in waste water or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

6. Further information

What Dolutegravir (as sodium) 50mg Tablet contains

The active substance in Dolutegravir Tablets 50mg is dolutegravir (as sodium).

The other ingredients of Dolutegravir Tablets 50mg are;

Core tablet: Mannitol, Microcrystalline cellulose Povidone, Sodium starch glycolate, and Sodium stearyl fumarate.

Film coated: Polyvinyl alcohol, Macrogol/polyethylene glycol, Talc, Titanium dioxide, FD&C Blue #2 / Indigo Carmine AL, D&C Yellow #10 Aluminum Lake

What Dolutegravir Tablets 50mg looks like and contents of the pack

Dolutegravir Tablets 50mg is green colored, round shaped, biconvex; film coated Tablet debossed with 'C' on one side and '90' on the other side.

Bottle packs : Tablets are packed in round white opaque HDPE bottle with child resistant polypropylene cap.

Pack sizes: 30, 60 or 90 tablets.

Applicant/Supplier and Manufacturer

Supplier

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For any information about this medicine, please contact the Applicant/Supplier:

This leaflet was last approved in {MM/YYYY}

< Detailed information on this medicinal product is available on PQTm's website (see: <http://www.who.int/prequal>).>