

PACKAGE LEAFLET

DOLUTEGRAVIR TABLETS 50 mg

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet

1. What Dolutegravir Tablets is and what it is used for
2. Before you take Dolutegravir Tablets
3. How to take Dolutegravir Tablets
4. Possible side effects
5. How to store Dolutegravir Tablets
6. Further information

Dolutegravir Tablets

Dolutegravir Tablets contains the active ingredient dolutegravir. Dolutegravir belongs to a group of anti-retroviral medicines called *integrase inhibitors (INIs)*.

Dolutegravir 50mg Tablets is used to treat HIV (human immunodeficiency virus) infection in adults and young people who weigh at least 40 kg.

Dolutegravir Tablets does not cure HIV infection; it reduces the amount of virus in your body, and keeps it at a low level. As a result of that, 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 Dolutegravir Tablets in the same way. Your doctor will monitor the effectiveness of your treatment.

Dolutegravir Tablets is always used in combination with other anti-retroviral medicines (*combination therapy*). To control your HIV infection, and to stop your illness from getting worse, you must keep taking all your medicines, unless your doctor tells you to stop taking any.

The Marketing Authorisation Holder for **Dolutegravir Tablets** is:

M/s Aurobindo Pharma Ltd

Plot No.: 2, Maitrivihar
Ameerpet, Hyderabad-500 038
Telangana State,
India.

Dolutegravir Tablets are manufactured by:

M/s Aurobindo Pharma Limited,
Unit VII, SEZ, TSIIC, Plot. No. S1,
S.No's: 411, 425, 434, 435 & 458,
Green Industrial Park, Polepally Village,
JedcherlaMandal, Mahaboobnagar District,
Telangana State, India.

1. What Dolutegravir Tablets are and what it is used for

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2. Before you take Dolutegravir Tablets

Donot take Dolutegravir Tablets:

- 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 doctor.

Warnings and precautions

Look out for important symptoms

Some people taking medicines for HIV infection develop other conditions, which can be

serious. These include:

- symptoms of 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 Tablets.

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

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

Do not give this medicine to children under 12 years of age, weighing less than 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.

Other medicines and Dolutegravir Tablets

Tell your doctor if you are taking, have recently taken or are planning to take any other medicines. This includes herbal medicines and other medicines bought without a prescription.

Do not take Dolutegravir Tablets with the following medicine:

- dofetilide, used to treat **heart conditions**

Some medicines can affect how Dolutegravir Tablets works, or make it more likely that you will have side effects. Dolutegravir Tablets can also affect how some other medicines work.

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 Dolutegravir Tablets, or for at least 2 hours after you take it. (*See also Section 3*).
- Calcium supplements, iron supplements and multivitamins. **Do not take a calcium supplement, iron supplement or multivitamin** during the 6 hours before you take Dolutegravir Tablets, or for at least 2 hours after you take it (*see also Section 3*).
- Etravirine, efavirenz, fosamprenavir/ritonavir, nevirapine or tipranavir/ritonavir, to treat

HIV infection

- Rifampicin, to treat tuberculosis (TB) and other **bacterial infections**
- Phenytoin and phenobarbital, to treat **epilepsy**

- Oxcarbamazepine and carbamazepine, to treat **epilepsy** or **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, if you become pregnant, or if you are planning to have a baby:

- **Talk to your doctor** about the risks and benefits of taking Dolutegravir Tablets.

Be sure to tell your health care provider immediately if you are pregnant or may be pregnant.

Breast-feeding

Women who are HIV-positive must not breast feed because HIV infection can be passed on to the baby in breast milk.

It is not known whether the ingredients of Dolutegravir Tablets can pass into your breast milk.

If you are breast-feeding, or thinking about breast-feeding:

- **Talk to your doctor immediately.**

Driving and using machines

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

- Don't drive or operate machinery unless you are sure you're not affected.

Dolutegravir 50mg Tablets contains sodium

Dolutegravir 50mg Tablets contains 3.976 mg of sodium which is less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Dolutegravir Tablets

Always take this medicine exactly as your doctor has told you. Do not stop taking it without checking with your health care provider. Check with your doctor or pharmacist if you are not sure.

- The usual dose is one 50 mg tablet **once a day**; if you are taking certain **other medicines** (see section 2, earlier in this leaflet), the dose is one 50 mg tablet **twice a day**; or

- **For the treatment of HIV that is resistant** to other medicines similar to Dolutegravir Tablets, the usual dose of Dolutegravir Tablets is one 50 mg tablet, **twice a day**.

Your doctor will decide on the correct dose of Dolutegravir Tablets for you.

Swallow the tablet with some liquid. Dolutegravir Tablets can be taken with or without food.

When Dolutegravir Tablets is taken twice a day, your doctor may advise you to take with food.

Use in children and adolescents

Children and adolescents aged between 12 and 17 years and weighing at least 40 kg can take

the adult dose of one tablet (50 mg), once a day. Dolutegravir Tablets should not be used in children and adolescents with **HIV infection that is resistant** to other medicines similar to Dolutegravir Tablets.

Antacid medicines

Antacids, to treat indigestion and heartburn, can stop Dolutegravir Tablets being absorbed into your body and make it less effective.

Do not take an antacid during the 6 hours before you take Dolutegravir Tablets, 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 Dolutegravir Tablets.

→ Talk to your doctor for further advice on taking acid-lowering medicines with Dolutegravir Tablets.

Calcium supplements, iron supplements or multivitamins

Calcium supplements, iron supplements or multivitamins can stop Dolutegravir Tablets being absorbed into your body and make it less effective.

Do not take a calcium supplement, iron supplement or multivitamin during the 6 hours before you take Dolutegravir Tablets, or for at least 2 hours after you take it.

→ Talk to your doctor for further advice on taking calcium supplements, iron supplements or multivitamins with Dolutegravir Tablets.

Dolutegravir 50mg Tablets 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 than you should

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

If you forget to take Dolutegravir Tablets

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.

Don't stop taking Dolutegravir Tablets without advice from your doctor

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, but 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 Dolutegravir Tablets 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.

Allergic reactions

These are uncommon in people taking Dolutegravir Tablets. Signs include:

- 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.

→ **See a doctor straight away.** Your doctor may decide to carry out tests on your liver, kidneys or blood, and may tell you to stop taking Dolutegravir Tablets.

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**:

- Rash
- itching (*pruritus*)
- being sick (*vomiting*)
- Stomach pain (*abdominal pain*)
- Stomach (*abdominal*) discomfort
- Insomnia
- Dizziness
- Abnormal dreams
- Depression (feelings of deep sadness and unworthiness)
- Lack of energy (*fatigue*)
- wind (*flatulence*)
- Increase in the level of liver enzymes
- Increase in the level of enzymes produced in the muscles (*creatine phosphokinase*).

Uncommon side effects

These 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

If you get any side effects

→ **Talk to your doctor.** This includes any possible side effects not listed in this leaflet.

Other possible side effects

People taking combination therapy for HIV may get other side effects.

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*). Such infections may have been “silent” and not detected by the weak immune system before treatment was started. 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**, plus some of the following:

- Headache
- Stomach ache
- Difficulty breathing

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) or tremor
- Hyperactivity (excessive restlessness and movement)
- Weakness beginning in the hands and feet and moving up towards the trunk of the body.

If you get any symptoms of infection and inflammation or if you notice any of the symptoms above:

→ **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 die 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 Dolutegravir Tablets

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

Do not use this medicine after the expiry date which is stated after EXP on the carton and bottle.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Further information

What Dolutegravir Tablets contains

- The active substance is dolutegravir. Each tablet contains dolutegravir sodium equivalent to 50 mg dolutegravir.
- The other ingredients in the tablet are Mannitol, Microcrystalline Cellulose, Povidone, Sodium Starch Glycolate, Sodium Stearyl Fumarate.
- The other ingredients in the tablet film coating are Poly Vinyl Alcohol, Macrogol 3350, Titanium dioxide, Talc, Iron oxide red.

What Dolutegravir Tablets looks like and contents of the pack

Dolutegravir Tablets are reddish brown colored, round, biconvex, film coated tablets debossed with 'T over 50' on one side and plain on the other side.

The film-coated tablets are provided in bottles containing 30 tablets.

Reporting of side effects

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

“If you notice any side effect (s) with the use of this drug, please report it immediately via internet to the following e-mail address: pharmacovigilance@aurobindo.com”.