PACKAGE LEAFLET

Package leaflet: Information for the patient

Dolutegravir Teva 50 mg film-coated tablets

dolutegravir

Read all of this leaflet carefully before you (or your child, if they are the patient) 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 (or your child, if they are the patient) 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.

What is in this leaflet

1. What Dolutegravir Teva is and what it is used for
2. What you need to know before you take Dolutegravir Teva
3. How to take Dolutegravir Teva
4. Possible side effects
5. How to store Dolutegravir Teva
6. Contents of the pack and other information

1. What Dolutegravir Teva is and what it is used for

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

Dolutegravir Teva is used to treat HIV (human immunodeficiency virus) infection in adults, adolescents and children of at least 6 years of age or older, and who weigh at least 14 kg.

Dolutegravir Teva 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 Teva in the same way. Your doctor will monitor the effectiveness of your treatment.

Dolutegravir Teva 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.

2. What you need to know before you take Dolutegravir Teva

Do not take Dolutegravir Teva
- if you (or your child, if they are the patient) are allergic to dolutegravir or any of the other ingredients of this medicine (listed in section 6).
- if you (or your child) are taking another medicine called fampridine (also known as dalfampridine; used in multiple sclerosis).

If you think any of these apply to you (or your child), tell your doctor.

Warnings and precautions
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 (or your child, if they are the patient) are taking Dolutegravir Teva.

Read the information in Section 4 of this leaflet.

Talk to your doctor or pharmacist before taking Dolutegravir Teva.

Children

Do not give this medicine to children under 6 years of age, weighing less than 14 kg or with HIV infection that is resistant to other medicines similar to Dolutegravir Teva. The use of Dolutegravir Teva film-coated tablets in children under 6 or weighing less than 14 kg has not yet been studied.

Children must keep planned doctor's appointments (see "Use in children and adolescents" in Section 3 for more information).

Other medicines and Dolutegravir Teva
Tell your doctor if you (or your child) are taking, have recently taken or are planning to take any other medicines.

Do not take Dolutegravir Teva with the following medicine:
- fampridine (also known as dalfampridine), used in multiple sclerosis.

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

Tell your doctor if you (or your child) 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 Teva, or for at least 2 hours after you take it. (*See also Section 3).*
- supplements or multivitamins containing calcium, iron or magnesium. If you take Dolutegravir Teva with food, you can take supplements or multivitamins containing calcium, iron or magnesium at the same time as Dolutegravir Teva. If you do not take Dolutegravir Teva with food, do not take a supplement or multivitamin containing calcium, iron or magnesium during the 6 hours before you take Dolutegravir Teva, 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
- oxcarbazepine and carbamazepine, to treat epilepsy or bipolar disorder
- St. John's wort (*Hypericum perforatum*), a herbal remedy to treat depression

Tell your doctor if you (or your child) are taking, have recently taken or are planning to take any other medicines.

Pregnancy
If you are pregnant, think you may be pregnant, or if you are planning to have a baby:
Talk to your doctor about the risks and benefits of taking Dolutegravir Teva.

Tell your doctor immediately if you become pregnant or are planning to become pregnant. Your doctor will review your treatment. Do not stop taking Dolutegravir Teva without consulting your doctor, as this may harm you and your unborn child.

Breast-feeding
Breast-feeding is not recommended in women living with HIV because HIV infection can be passed on to the baby in breast milk.
A small amount of the ingredient in Dolutegravir Teva can pass into your breast milk.

If you are breast-feeding, or thinking about breast-feeding, you should discuss it with your doctor as soon as possible.

Driving and using machines
Dolutegravir Teva 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 Teva contains sodium
Dolutegravir Teva contains less than 1 mmol sodium (23 mg) per tablet, that is to say is essentially 'sodium-free.'

3. How to take Dolutegravir Teva

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- The usual dose is 50 mg once a day.
- If you are taking certain other medicines, the dose is 50 mg twice a day.
- For HIV that is resistant to other medicines similar to Dolutegravir Teva, the usual dose is 50 mg, twice a day.

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

Swallow the tablet(s) with some liquid.

Dolutegravir Teva can be taken with or without food. When Dolutegravir Teva is taken twice a day, your doctor may advise you to take with food.

Dolutegravir is also available as dispersible tablets. Film-coated tablets and dispersible tablets are not the same, therefore do not switch between film-coated tablets and dispersible tablets without first talking to your doctor.

Use in children and adolescents
- Children's dose of Dolutegravir Teva needs to be adjusted as they get older or gain weight. It is important therefore that children keep planned doctor's appointments.
- Children and adolescents weighing at least 20 kg can take the adult dose of 50 mg, once a day. Your doctor will decide how Dolutegravir Teva should be given.
- For children aged between 6 and 12 years your doctor will decide on the correct dose of Dolutegravir Teva, depending on the weight of your child.
- To reduce the risk of choking, children must not swallow more than one tablet at a time.
- Dolutegravir Teva should not be used in children and adolescents with HIV infection that is resistant to other medicines similar to Dolutegravir Teva.

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

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

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

Supplements or multivitamins containing calcium, iron or magnesium
Supplements or multivitamins containing calcium, iron or magnesium can stop Dolutegravir Teva being absorbed into your body and make it less effective.

If you take Dolutegravir Teva with food, you can take supplements or multivitamins containing calcium, iron or magnesium at the same time as Dolutegravir Teva. If you do not take Dolutegravir Teva with food, do not take a supplement or multivitamin containing calcium, iron or magnesium during the 6 hours before you take Dolutegravir Teva, or for at least 2 hours after you take it.

Talk to your doctor for further advice on taking supplements or multivitamins containing calcium, iron or magnesium with Dolutegravir Teva.

If you take more Dolutegravir Teva than you should
If you (or your child) take too many tablets of Dolutegravir Teva, contact your doctor or pharmacist for advice. If possible, show them the Dolutegravir Teva pack.

If you forget to take Dolutegravir Teva
If you (or your child) 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.

Do not take a double dose to make up for a forgotten tablet.

If you stop taking Dolutegravir Teva
Do not stop taking Dolutegravir Teva without advice from your doctor. Take Dolutegravir Teva 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, although not everybody gets them.

Allergic reactions
These are uncommon in people taking Dolutegravir Teva. 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.

You must immediately contact your doctor if you experience any of those following serious side effects. Your doctor may decide to carry out tests on your liver, kidneys or blood, and may tell you to stop taking Dolutegravir Teva.

Very common side effects: may affect more than 1 in 10 people:
- headache
- diarrhoea
- feeling sick (nausea)

Common side effects: may affect up to 1 in 10 people:
- rash
- itching (pruritus)
- being sick (vomiting)
- stomach pain (abdominal pain)
- stomach (abdominal) discomfort
- weight gain
- insomnia
- dizziness
- abnormal dreams
- depression (feelings of deep sadness and unworthiness)
- anxiety
- 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: may affect up to 1 in 100 people:
- inflammation of the liver (hepatitis)
- suicide attempt*
- suicidal thoughts*
- panic attack
- joint pain
- muscle pain

** particularly in patients who have had depression or mental health problems before.*

Rare side effects: may affect up to 1 in 1 000 people:
- liver failure (signs may include yellowing of the skin and the whites of the eyes or unusually dark urine)
- increase in bilirubin (a test of liver function) in your blood.
- suicide (particularly in patients who have had depression or mental health problems before)**

***You must immediately contact your doctor if you experience any mental health problems (see also other mental health problems above).*

Frequency not known: cannot be estimated from the available data:
- a condition where red blood cells do not form properly (*sideroblastic anaemia*).

Some side effects could be serious. You must immediately contact your doctor if you experience any of those following serious 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 (or your child) get any symptoms of infection and inflammation or if you notice any of the symptoms above, you must immediately contact your doctor. Do not 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, you must immediately contact your doctor.

Weight, blood lipid and blood glucose effects

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and lifestyle, and sometimes to the HIV medicines themselves. Your doctor will test for these changes.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dolutegravir Teva

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

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

This medicine does not require any special storage conditions.

Do not use this medicine if its pack is damaged or shows signs of tampering.

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. Contents of the pack and other information

What Dolutegravir Teva contains

- The active substance is dolutegravir. Each tablet contains dolutegravir sodium equivalent to 50 mg dolutegravir.
- The other ingredients are mannitol (E421), cellulose, microcrystalline (E460i), povidone K30, sodium starch glycolate (Type A), sodium stearyl fumarate, poly(vinyl alcohol) (E1203), titanium dioxide (E171), macrogol 3350 (E1521), talc (E553b), iron oxide yellow (E172).

What Dolutegravir Teva looks like and contents of the pack

Dolutegravir Teva 50 mg film-coated tablets are yellow, round (9 mm in diameter), biconvex film-coated tablets debossed with '50' on one side.

Dolutegravir Teva is available in OPA/Alu/PVC//Alu blisters containing 30 film-coated tablets, OPA/Alu/PVC//Alu perforated unit-dose blisters containing 30 x 1 or 90 x 1 film-coated tablets.

White HDPE twist-off bottle with a white child-resistant polypropylene screw closure and silica gel canister containing 30 or 90 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Teva GmbH,
Graf-Arco-Straße 3,
89079 Ulm, Germany

Manufacturers

Elpen Pharmaceutical Co. Inc. Marathonos Avenue 95, Pikermi, 190 09, Greece.

Elpen Pharmaceutical Co. Inc. Zapani, Block 1048, Keratea, 190 01, Greece.

This medicine is authorised in the Member States of the European Economic under the following names:

Member State	Product Name
Netherland	Dolutegravir Teva 50 mg, filmomhulde tabletten
Austria	Dolutegravir ratiopharm 50 mg Filmtabletten
Belgium	Dolutegravir Teva 50 mg filmomhulde tabletten/comprimés pelliculés/Filmtabletten
Czech Republic	Dolutegravir Teva
Germany	Dolutegravir-ratiopharm 50 mg Filmtabletten
Denmark	Dolutegravir Teva
Estonia	Dolutegravir Teva

Spain	Dolutegravir Teva 50 mg comprimidos recubiertos con película EFG
France	DOLUTEGRAVIR TEVA 50 mg, comprimé pelliculé
Croatia	Dolutegravir Teva 50 mg filmom obložene tablete
Hungary	Dolutegravir Teva 50 mg filmtabletta
Ireland	Dolutegravir Teva 50 mg film-coated tablets
Iceland	Dolutegravir Teva
Italy	Dolutegravir Teva
Lithuania	Dolutegravir Teva 50 mg plėvele dengtos tabletės

This leaflet was last revised in June 2026.