

PACKAGE LEAFLET

Package leaflet: Information for the patient

Dolutegravir Teva 50 mg, filmomhulde tabletten

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

1. What <PRODUCT NAME> is and what it is used for

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

<PRODUCT NAME> 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.

<PRODUCT NAME> 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 <PRODUCT NAME> in the same way. Your doctor will monitor the effectiveness of your treatment.

<PRODUCT NAME> 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 <PRODUCT NAME>

Do not take <PRODUCT NAME>

- 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 <PRODUCT NAME>.

Read the information in Section 4 of this leaflet.

Talk to your doctor or pharmacist before taking <PRODUCT NAME>.

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 <PRODUCT NAME>. The use of <PRODUCT NAME> 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 <PRODUCT NAME>

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

Do not take <PRODUCT NAME> with the following medicine:

- fampridine (also known as dalfampridine), used in multiple sclerosis.

Some medicines can affect how <PRODUCT NAME> works, or make it more likely that you will have side effects. <PRODUCT NAME> 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 <PRODUCT NAME>, 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 <PRODUCT NAME> with food, you can take supplements or multivitamins containing calcium, iron or magnesium at the same time as <PRODUCT NAME>. If you do not take <PRODUCT NAME> with food, do not take a supplement or multivitamin containing calcium, iron or magnesium during the 6 hours before you take <PRODUCT NAME>, 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 <PRODUCT NAME>.

Tell your doctor immediately if you become pregnant or are planning to become pregnant. Your doctor will review your treatment. Do not stop taking <PRODUCT NAME> 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 <PRODUCT NAME> 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

<PRODUCT NAME> 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.

<PRODUCT NAME> contains sodium

<PRODUCT NAME> contains less than 1 mmol sodium (23 mg) per tablet, that is to say is essentially 'sodium-free.'

3. How to take <PRODUCT NAME>

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 <PRODUCT NAME>, the usual dose is 50 mg, twice a day.

Your doctor will decide on the correct dose of <PRODUCT NAME> for you.

Swallow the tablet(s) with some liquid.

<PRODUCT NAME> can be taken with or without food. When <PRODUCT NAME> 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 <PRODUCT NAME> 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 <PRODUCT NAME> should be given.
- For children aged between 6 and 12 years your doctor will decide on the correct dose of <PRODUCT NAME>, depending on the weight of your child.
- To reduce the risk of choking, children must not swallow more than one tablet at a time.
- <PRODUCT NAME> should not be used in children and adolescents with HIV infection that is resistant to other medicines similar to <PRODUCT NAME>.

Antacid medicines

Antacids, to treat indigestion and heartburn, can stop <PRODUCT NAME> being absorbed into your body and make it less effective.

Do not take an antacid during the 6 hours before you take <PRODUCT NAME>, 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 <PRODUCT NAME>.

Talk to your doctor for further advice on taking acid-lowering medicines with <PRODUCT NAME>.

Supplements or multivitamins containing calcium, iron or magnesium

Supplements or multivitamins containing calcium, iron or magnesium can stop <PRODUCT NAME> being absorbed into your body and make it less effective.

If you take <PRODUCT NAME> with food, you can take supplements or multivitamins containing calcium, iron or magnesium at the same time as <PRODUCT NAME>. If you do not take <PRODUCT NAME> with food, do not take a supplement or multivitamin containing calcium, iron or magnesium during the 6 hours before you take <PRODUCT NAME>, 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 <PRODUCT NAME>.

If you take more <PRODUCT NAME> than you should

If you (or your child) take too many tablets of <PRODUCT NAME>, contact your doctor or pharmacist for advice. If possible, show them the <PRODUCT NAME> pack.

If you forget to take <PRODUCT NAME>

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 <PRODUCT NAME>

Do not stop taking <PRODUCT NAME> without advice from your doctor. Take <PRODUCT NAME> 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 <PRODUCT NAME>. 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 <PRODUCT NAME>.

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 [the national reporting system listed in Appendix V](#).^{*} By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <PRODUCT NAME>

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 <PRODUCT NAME> 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 <PRODUCT NAME> looks like and contents of the pack

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

<PRODUCT NAME> 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
Duitsland

Manufacturer

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

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

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

België	Dolutegravir Teva 50 mg filmomhulde tabletten/comprimés pelliculés/Filmtabletten
Duitsland	Dolutegravir-ratiopharm 50 mg Filmtabletten
Frankrijk	DOLUTEGRAVIR TEVA 50 mg, comprimé pelliculé
Hongarije	Dolutegravir Teva 50 mg filmtabletta
Ierland	Dolutegravir Teva 50 mg film-coated tablets
Kroatië	Dolutegravir Teva 50 mg filmom obložene tablete
Litouwen	Dolutegravir Teva 50 mg plėvele dengtos tabletės
Letland	Dolutegravir Teva 50 mg apvalkotās tabletes
Nederland	Dolutegravir Teva 50 mg, filmomhulde tabletten

Oostenrijk	Dolutegravir ratiopharm 50 mg Filmdabletten
Roemenië	Dolutegravir Teva 50 mg comprimate filmate
Spanje	Dolutegravir Teva 50 mg comprimidos recubiertos con película EFG
Tsjechië, Denemarken, Estland, IJsland, Italië, Noorwegen, Portugal, Zweden: Dolutegravir Teva	

Deze bijsluiter is voor het laatst goedgekeurd in juli 2026.

Other sources of information

<Latest approved information on this medicine is available by scanning the QR code included in the <package leaflet> <outer carton> with a smartphone/device. The same information is also available on the following URL: [URL to be included] <and the <NCA> website>>

In case that only the URL is mentioned in the PI and not linked via mobile technology, please include:
<Latest approved information on this product is available on the following URL: [URL to be included] <and the <NCA> website>>