

Package leaflet: Information for the patient

Dolutegravir ELPEN 25 mg film-coated tablets **Dolutegravir ELPEN 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 <Invented Name> is and what it is used for
2. What you need to know before you take <Invented Name>
3. How to take <Invented Name>
4. Possible side effects
5. How to store <Invented Name>
6. Contents of the pack and other information

1. What <Invented Name> is and what it is used for

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

<Invented 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.

<Invented 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 <Invented Name> in the same way. Your doctor will monitor the effectiveness of your treatment.

<Invented 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 <Invented Name>

Do not take <Invented 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

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 (or your child, if they are the patient) are taking <Invented Name>.

→ **Read the information in Section 4 of this leaflet.**

Children

Do not give this medicine to children under 6 years of age, weighing less than 20 kg or with HIV infection that is resistant to other medicines similar to <Invented Name>. The use of 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 <Invented Name>

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

Don't take <Invented Name> with the following medicine:

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

Some medicines can affect how <Invented Name> works, or make it more likely that you will have side effects. <Invented 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 <Invented 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 <Invented Name> with food**, you can take supplements or multivitamins containing calcium, iron or magnesium at the same time as <Invented Name>. **If you do not take <Invented Name> with food, do not take a supplement or multivitamin containing calcium, iron or magnesium** during the 6 hours before you take <Invented 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 or pharmacist** if you (or your child) are taking any of these. Your doctor may decide to adjust your dose or that you need extra check ups.

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 <Invented 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 <Invented 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 <Invented 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

<Invented 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.

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

3. How to take <Invented 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 <Invented Name>, the usual dose is 50 mg, **twice a day**.

Your doctor will decide on the correct dose of <Invented Name> for you.

Swallow the tablet(s) with some liquid.

<Invented Name> can be taken **with or without food**. When <Invented Name> is taken twice a day, your doctor may advise you to take with food.

<Invented Name> is also available in other pharmaceutical forms. Film-coated tablets and the other pharmaceutical forms are not the same, therefore **do not switch** between film-coated tablets and different pharmaceutical forms without first talking to your doctor.

Use in children and adolescents

- **Children's dose** of <Invented 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 or 25 mg twice daily. Your doctor will decide how <Invented Name> should be given.
- For children aged between 6 and 12 years your doctor will decide on the correct dose of dolutegravir depending on the weight of your child.
- To reduce the risk of choking, children **must not swallow more than one tablet at a time**.
- <Invented Name> should **not** be used in children and adolescents with **HIV infection that is resistant** to other medicines similar to <Invented Name>.

Antacid medicines

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

Do not take an antacid during the 6 hours before you take <Invented 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 <Invented Name>.

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

Supplements or multivitamins containing calcium, iron or magnesium

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

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

If you take more <Invented Name> than you should

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

If you forget to take <Invented 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.

Don't take a double dose to make up for a missed dose.

Don't stop taking <Invented Name> without advice from your doctor

Take <Invented 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, but not everybody gets them.

Allergic reactions

These are uncommon in people taking <Invented 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.
- **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 <Invented Name>.

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
- 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

These 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

These may affect **up to 1 in 1000 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)

→ **Tell your doctor immediately** 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*).

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:

→ **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.**

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 <Invented Name>

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. Contents of the pack and other information

What <Invented Name> contains

- The active substance is dolutegravir. Each tablet contains dolutegravir sodium equivalent to mg, 25 mg or 50 mg dolutegravir.
- The other ingredients are mannitol, microcrystalline cellulose, povidone K30, sodium starch glycolate, sodium stearyl fumarate, poly(vinyl alcohol)(E1203), titanium dioxide (E171), macrogol 3350 (E1521), talc (E553b) and iron oxide yellow (E172).

What <Invented Name> looks like and contents of the pack

<Invented Name> 25 mg film-coated tablets are pale yellow, round, biconvex film-coated tablets, approximately 7 mm in diameter, debossed with '25' on one side and plain on the other side

<Invented Name> 50 mg film-coated tablets are yellow, round, biconvex film-coated tablets, approximately 9 mm in diameter, debossed with '50' on one side and plain on the other side

The following pack sizes are available:

- Blister packs contain 30 or 90 film-coated tablets.
- Bottles contain 30 film coated tablets. The bottles contain a desiccant canister to reduce moisture. Once the bottle has been opened keep the desiccant canister in the bottle, do not remove it.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

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

<{Name of the Member State}> <{Name of the medicine}>

<{Name of the Member State}> <{Name of the medicine}>

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