

Package leaflet: Information for the patient

Juluca 50 mg/25 mg film-coated tablets dolutegravir/rilpivirine

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.

What is in this leaflet

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

1. What Juluca is and what it is used for

Juluca is a medicine that contains two active ingredients used to treat human immunodeficiency virus (HIV) infection: dolutegravir and rilpivirine. Dolutegravir belongs to a group of anti-retroviral medicines called *integrase inhibitors (INIs)*, and rilpivirine belongs to a group of anti-retroviral medicines called *non-nucleoside reverse transcriptase inhibitors (NNRTIs)*.

Juluca is used to treat HIV in adults aged 18 years and over who are taking other antiretroviral medicines and whose HIV-1 infection is under control for at least 6 months. Juluca may replace your current antiretroviral medicines.

Juluca keeps the amount of HIV virus in your body at a low level. This helps maintain the number of CD4 cells in your blood. CD4 cells are a type of white blood cells that are important in helping your body to fight infection.

2. What you need to know before you take Juluca

Do not take Juluca:

- if you are allergic to dolutegravir or rilpivirine or any of the other ingredients of this medicine (listed in section 6).

Do not take Juluca if you are taking any of the following medicines as they may affect the way Juluca works:

- fampridine (also known as dalfampridine; used in multiple sclerosis)
- carbamazepine, oxcarbazepine, phenobarbital, phenytoin (medicines to treat epilepsy and to prevent fits)
- rifampicin, rifapentine (medicines to treat some bacterial infections such as tuberculosis)
- omeprazole, esomeprazole, lansoprazole, pantoprazole, rabeprazole, (medicines to prevent and treat stomach ulcers, heartburn or acid reflux disease)
- dexamethasone (a corticosteroid used in many conditions such as inflammation and allergic reactions) when taken by mouth or injected, except as a single dose treatment
- products that contain St John's wort (*Hypericum perforatum*) (a herbal product used for depression).

If you are taking any of the above, ask your doctor about alternatives.

Warnings and precautions

Talk to your doctor or, pharmacist before taking Juluca.

Allergic reactions

Juluca contains dolutegravir. Dolutegravir can cause a serious allergic reaction known as a hypersensitivity reaction. You need to know about important signs and symptoms to look out for while you're taking Juluca.

→ **Read the information** 'Allergic reactions' in section 4 of this leaflet.

Liver problems including hepatitis B and/or C

Tell your doctor if you have or have had **problems with your liver**, including hepatitis B and/or C. Your doctor may evaluate how severe your liver disease is before deciding if you can take Juluca.

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 Juluca.

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

Children and adolescents

This medicine is not for use in children or adolescents less than 18 years of age, because it has not been studied in these patients.

Other medicines and Juluca

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Juluca must not be taken with some other medicines (see 'Do not take Juluca' earlier in section 2).

Some medicines can affect how Juluca works, or make it more likely that you will have side effects. Juluca 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 that may cause a life threatening irregular heartbeat (*Torsade de Pointes*). As a number of different medicines can cause this condition, you should ask your doctor or pharmacist if you are not sure
- medicines called **antacids**, to treat **indigestion** and **heartburn**. **Do not take an antacid** during the 6 hours before you take Juluca, or for at least 4 hours after you take it (see also section 3, 'How to take Juluca')
- **calcium supplements, iron supplements and multivitamins** must be taken at the same time as Juluca with a meal. If you can't take these supplements at the same time as Juluca, **do not take a calcium supplement, iron supplement or multivitamin** during the 6 hours before you take Juluca, or for at least 4 hours after you take it (see also section 3, 'How to take Juluca')
- medicines called **H₂ receptor antagonists** (for example cimetidine, famotidine, nizatidine, ranitidine) to treat stomach or **intestinal ulcers** or used to **relieve heartburn due to acid reflux**. **Do not take these medicines** during the 12 hours before you take Juluca, or for at least 4 hours after you take it (see also section 3, 'How to take Juluca')
- any medicines to treat **HIV infection**

- rifabutin, to treat tuberculosis (TB) and other **bacterial infections**. If you take rifabutin, your doctor may need to give you an additional dose of rilpivirine to treat your HIV infection (see section 3, ‘How to take Juluca’)
- artemether/lumefantrine used to prevent you catching **malaria**
- clarithromycin and erythromycin, to treat **bacterial infections**
- methadone, used in the treatment of opioid dependence
- dabigatran etexilate, used to treat or prevent **blood clots**.

→ **Tell your doctor or pharmacist** if you are taking any of these. Your doctor may decide 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:

→ **Use of Juluca is not recommended. Ask your doctor** for advice.

Taking Juluca at the time of becoming pregnant or during the first six weeks of pregnancy, may also 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 Juluca:

→ **Talk to your doctor** and discuss whether there is a need for contraception, such as condom or pills.

Tell your doctor immediately if you become pregnant or are planning to become pregnant. Your doctor will review your treatment. Do not stop taking Juluca 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, dolutegravir, in Juluca can pass into your breast milk. It is not known whether the other ingredient, rilpivirine, 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

Juluca can make you dizzy, tired or drowsy and have other side effects that make you less alert.

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

Juluca contains lactose

If you have been told by your doctor that you have intolerance to some sugars, speak with your doctor before taking this medicine.

3. How to take Juluca

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- The recommended dose of Juluca is **one tablet once a day**. Juluca **must be taken with a meal**. A meal is important to get the right levels of medicine in your body. A protein-rich nutritional drink alone does not replace a meal.
- Do not chew, crush or split the tablet, to ensure the full dose is taken.

Rifabutin

Rifabutin, a medicine to treat some bacterial infections, can lower the amount of Juluca in your body and make it less effective.

If you take rifabutin, your doctor may need to give you an additional dose of rilpivirine. Take the rilpivirine tablet at the same time you take Juluca.

→ Talk to your doctor for further advice on taking rifabutin with Juluca.

Antacid medicines

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

Do not take an antacid during the 6 hours before you take Juluca, or for at least 4 hours after you take it.

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

Calcium supplements, iron supplements or multivitamins

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

Calcium supplements, iron supplements or multivitamins must be taken at the same time as Juluca. Juluca must be taken with a meal.

If you can't take these supplements at the same time as Juluca, do not take calcium supplements, iron supplements or multivitamins during the 6 hours before you take Juluca, or for at least 4 hours after you take it.

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

H₂ receptor antagonists (for example cimetidine, famotidine, nizatidine, ranitidine)

H₂ receptor antagonist medicines can stop Juluca being absorbed into your body and make it less effective.

Do not take these medicines during the 12 hours before you take Juluca, or for at least 4 hours after you take it.

→ Talk to your doctor for further advice on taking these medicines with Juluca.

If you take more Juluca than you should

If you take too many tablets of Juluca **contact your doctor or pharmacist immediately**. If possible, show them the Juluca pack.

If you forget to take Juluca

If you notice within 12 hours of the time you usually take Juluca, you must take the tablet as soon as possible. The Juluca tablet must be taken with a meal. Then take the next dose as usual. If you notice after 12 hours, then skip that dose and take the next doses as usual.

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

If you vomit less than 4 hours after taking Juluca, take another tablet with a meal. If you vomit more than 4 hours after taking Juluca you do not need to take another tablet until your next scheduled dose.

Don't stop taking Juluca without advice from your doctor

Take Juluca for as long as your doctor recommends. Don't stop unless your doctor tells 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, **so it is very important to talk to your doctor about any changes in your health**.

Allergic reactions

Juluca contains dolutegravir. Dolutegravir can cause a serious allergic reaction known as a *hypersensitivity reaction*. This is an uncommon (may affect up to 1 in 100 people) reaction in people taking dolutegravir. If you get any of the following symptoms:

- 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 to check your liver, kidneys or blood, and may tell you to stop taking Juluca.

Very common side effects

These may affect **more than 1 in 10 people**:

- headache
- dizziness
- diarrhoea
- feeling sick (*nausea*)
- difficulty in sleeping (*insomnia*).

Very common side effects that may show up in blood tests are:

- increase in the level of liver enzymes (aminotransferases)
- increase in cholesterol
- increase in pancreatic amylase (a digestive enzyme).

Common side effects

These may affect **up to 1 in 10 people**:

- loss of appetite
- rash
- itching (*pruritus*)
- being sick (*vomiting*)
- stomach (*abdominal*) pain or discomfort
- weight gain
- wind (*flatulence*)
- feeling drowsy
- sleep disorders
- abnormal dreams
- lack of energy (*fatigue*)
- depression (feelings of deep sadness and unworthiness)
- depressed mood
- anxiety
- dry mouth.

Common side effects that may show up in blood tests are:

- increase in the level of enzymes produced in the muscles (creatine phosphokinase).
- decreased number of platelets, which are involved in blood clotting
- low white blood cell count
- decrease in haemoglobin
- increase in triglycerides (a type of fat)
- increase in lipase (an enzyme involved in breaking down fats)
- increase in bilirubin (a test of liver function) in your blood.

Uncommon side effects

These may affect **up to 1 in 100 people**:

- allergic (*hypersensitivity*) reaction (see ‘allergic reactions’ earlier in this section)
- inflammation of the liver (*hepatitis*)
- suicidal thoughts and behaviours (particularly in patients who have had depression or mental health problems before)
- panic attack
- joint pain
- muscle pain.

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).
- 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).

Not known

Frequency cannot be estimated from the available data:

- signs or symptoms of inflammation or infection, for example fever, chills, sweats (*immune reactivation syndrome*).

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*). Symptoms of infection may develop, caused by old, hidden infections flaring up again as the body fights them. 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 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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Juluca

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 bottle after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture. Keep the bottle tightly closed. Do not remove the desiccant.

This medicine does not require any special temperature 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 Juluca contains

- The active substances are dolutegravir and rilpivirine. Each tablet contains dolutegravir sodium equivalent to 50 mg dolutegravir and rilpivirine hydrochloride equivalent to 25 mg rilpivirine.
- The other ingredients are mannitol (E421), magnesium stearate, microcrystalline cellulose, povidone (K29/32), sodium starch glycolate, sodium stearyl fumarate, lactose monohydrate, croscarmellose sodium, povidone (K30), polysorbate 20, silicified microcrystalline cellulose, polyvinyl alcohol- part hydrolysed, titanium dioxide (E171), macrogol, talc, iron oxide yellow (E172), iron oxide red (E172).
- This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

What Juluca looks like and contents of the pack

Juluca film-coated tablets are pink, oval, biconvex tablets debossed with 'SV J3T' on one side.

The film-coated tablets are provided in bottles closed with child-resistant closures.

Each bottle contains 30 film-coated tablets and a desiccant to reduce moisture. Once the bottle has been opened keep the desiccant in the bottle, do not remove it.
Multipacks containing 90 film-coated tablets (3 packs of 30 film-coated tablets) are also available.
Not all pack sizes may be available in your country.

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Other formats

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name **Juluca**
Reference number 35728/0034

This is a service provided by the Royal National Institute of Blind People.

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