

JULUCA

dolutegravir / rilpivirine combination tablet

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about JULUCA. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking JULUCA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What JULUCA is used for

JULUCA is used to treat HIV (human immunodeficiency virus) infection in adults.

Each JULUCA tablet contains two active ingredients that are used to treat HIV infection: dolutegravir and rilpivirine. Dolutegravir belongs to a group of anti-retroviral medicines called integrase inhibitors (INIs) Rilpivirine belongs to a group of anti-retroviral medicines called non-nucleoside analogue reverse transcriptase inhibitors (NNRTIs).

JULUCA does not cure HIV infection, it keeps the amount of 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 cell that are important in helping your body to fight infection.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

JULUCA is not addictive.

JULUCA is not recommended for children and adolescents under the age of 18 years.

JULUCA is only available with a doctor's prescription.

Before you take JULUCA

When you must not take it

Do not take JULUCA if:

- You have ever had an allergic reaction to any medicine containing dolutegravir or rilpivirine
- You are allergic to any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
 - Shortness of breath
 - Wheezing or difficulty breathing
 - Swelling of the face, lips tongue or other parts of the body
 - Rash, itching or hives on the skin.
- You are taking any of these medicines:
 - Dofetilide or pilsicainide (to treat heart conditions)
 - Fampridine (used in multiple sclerosis)

- Carbamazepine, oxcarbazepine, phenobarbital, or phenytoin (also known as anticonvulsants used to treat epilepsy and prevent seizures)
- Rifampicin or rifapentine (to treat some bacterial infections such as tuberculosis)
- Omeprazole, esomeprazole, lansoprazole, pantoprazole, or rabeprazole (proton pump inhibitors that are medicines to prevent and treat stomach ulcers, heartburn or acid reflux disease)
- Dexamethasone (a corticosteroid used in a variety of conditions such as inflammation and allergic reactions)
- Products that contain St John's wort (hypericum perforatum) (a herbal product used to treat depression).

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Some other conditions may develop during HIV treatment.

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). When they start treatment, the immune system becomes stronger, so the body starts to fight infections.

Symptoms of infection and inflammation may develop, caused by either:

- old, hidden infections flaring up again as the body fights them
- the immune system attacking 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:

- muscle weakness and/or muscle pain
- joint pain or swelling
- weakness beginning in the hands and feet and moving up towards the trunk of the body
- palpitations or tremor
- hyperactivity (excessive restlessness and movement).

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.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

If you are pregnant, or think you could be, or if you are planning to have a baby, don't take JULUCA without checking with your doctor.

Your doctor will consider the benefit to you and the risk to your baby of taking JULUCA while you're pregnant. If you could get pregnant while taking JULUCA, you need to use a reliable method of contraception to prevent pregnancy.

Taking dolutegravir (one of the components of JULUCA) at the time of becoming pregnant, or during the first twelve weeks of pregnancy, may increase the risk of a type of birth

defect, called neural tube defect, such as spina bifida (malformed spinal cord).

Your doctor can discuss with you the risks and benefits involved.

Where possible, women who are HIV-positive should not breast feed, because HIV infection can be passed on to the baby in breast milk.

It is not known whether the ingredients of JULUCA can pass into breast milk and harm your baby.

If you have not told your doctor about any of the above, tell him/her before you start taking JULUCA.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor or pharmacist if you are taking any of the medicines listed under "When you must not take it" or any of the medicines in the following list:

- metformin, to treat diabetes
- medicines called antacids, to treat indigestion and heartburn
- calcium and iron supplements (non-antacids)
- famotidine, cimetidine, nizatidine, and ranitidine (H₂-receptor antagonists) to treat indigestion and heartburn
- rifabutin, to treat some bacterial infections, such as tuberculosis (TB)
- clarithromycin, erythromycin, antibiotics used to treat bacterial infections
- methadone, a medicine used for pain
- efavirenz, etravirine, and nevirapine (non-nucleoside reverse transcriptase inhibitors [NNRTIs]) to treat HIV infection
- any other medicine to treat HIV infection.

These medicines may be affected by JULUCA or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take JULUCA

Follow all directions given to you by your doctor or pharmacist carefully.

If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

How much to take

The usual dose of JULUCA is one tablet (containing 50 mg dolutegravir and 25 mg rilpivirine) taken once a day with a meal.

How to take it

Swallow the tablet whole with some water.

Take JULUCA once a day with a meal.

Taking JULUCA with a meal is important to help get the right amount of medicine in your body. A protein-rich nutritional drink alone does not replace a meal.

Antacid medicines

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

JULUCA should be taken at least 4 hours before or 6 hours after you take an antacid. Talk to your doctor for further advice on taking acid-lowering (antacid) medicines with JULUCA.

Calcium or iron supplements (non-antacids)

Calcium or iron containing supplements can stop JULUCA being absorbed into your body and make it less effective.

JULUCA should be taken at least 4 hours before or 6 hours after you take a calcium or iron containing supplement. However, provided you take JULUCA with a meal, you can take calcium and iron supplements at the same time as JULUCA.

H2-receptor antagonists

H2-receptor antagonists (to treat indigestion and heartburn), such as famotidine, cimetidine, nizatidine, and ranitidine can stop JULUCA being absorbed into your body and make it less effective.

JULUCA should be taken at least 4 hours before or 12 hours after you take a H2-receptor antagonist.

Rifabutin

Rifabutin (to treat bacterial infections such as tuberculosis) can lower the amount of JULUCA in your body and make it less effective. If you are taking rifabutin, you must also take a 25 mg dose of rilpivirine at the same time as JULUCA.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

If you forget to take it

If you miss a dose, take it as soon as you remember. JULUCA must be taken with a meal. If it is less than 12 hours before your next dose, skip the dose you missed and

take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much JULUCA. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using JULUCA

You will need regular blood tests

For as long as you're taking JULUCA, your doctor will arrange regular blood tests to check for side effects.

Stay in regular contact with your doctor

JULUCA helps to control your condition, but it is not a cure for HIV infection. You need to keep taking it every day to stop your illness from getting worse. Because JULUCA does not cure HIV infection, you may still develop other infections and illnesses linked to HIV infection.

Keep in touch with your doctor and don't stop taking JULUCA without your doctor's advice.

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, which may include:

- Use a condom when you have oral or penetrative sex
- Don't risk blood transfer - for example, don't share needles.

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking JULUCA.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

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

Don't drive or use machines unless you are sure you're not affected.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking JULUCA.

This medicine helps most people with HIV, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

When you're being treated for HIV, it can be hard to tell whether a symptom is a side effect of JULUCA 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.

Some side effects may only be seen in your blood tests and may not appear immediately after you start taking JULUCA. If you get any of these effects, and if they are severe, your doctor may advise you to stop taking JULUCA.

As well as the effects listed below for JULUCA, other conditions can develop during therapy for HIV.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Allergic reactions

See a doctor as soon as possible if you develop a rash.

Allergic reactions are uncommon in people taking JULUCA. 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.

Your doctor may decide to carry out tests on 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
- Feeling sick (nausea)
- Diarrhoea.

Common side effects

These may affect up to 1 in 10 people:

- Decreased appetite
- Depression
- Anxiety
- Difficulty sleeping or difficulty falling asleep (insomnia)
- Abnormal dreams
- Sleep disorders
- Dizziness
- Stomach (abdominal) pains or discomfort
- Being sick (vomiting)
- Wind (flatulence)
- Rash
- Itching (pruritus)
- Lack of energy (fatigue)
- Increase in the level of liver enzymes (may be shown in blood tests).

Uncommon side effects

These may affect up to 1 in 100 people:

- Suicidal thoughts and behaviours (particularly in patients who have had depression or mental health problems before)
- Depressed mood
- Inflammation of the liver (hepatitis)
- Feeling drowsy
- Weight gain

- Allergic reaction (hypersensitivity) (see earlier in this section for more details)
- 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)

Other side effects that may show up in blood tests

Other side effects have occurred in some people but their exact frequency is unknown:

- increase in bilirubin (a substance produced by the liver) in the blood
- an increase in the level of enzymes produced in the muscles (creatine phosphokinase, creatinine).

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using JULUCA

Storage

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

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store JULUCA tablets or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

JULUCA tablets are pink, film coated, oval, biconvex tablets debossed with 'SV J3T' on one side. They are supplied in a white bottle which contains 30 tablets.

The bottle contains a desiccant (a small packet containing a substance to reduce moisture). Once the bottle is opened, keep the desiccant in the bottle, do not remove it.

Ingredients

JULUCA tablets contain 50 mg of dolutegravir (as sodium) and 25 mg rilpivirine (as hydrochloride) as the active ingredients.

JULUCA also contains the inactive ingredients:

- Mannitol
- Microcrystalline cellulose
- Povidone
- Sodium starch glycollate Type A
- Sodium stearyl fumarate
- Lactose monohydrate
- Croscarmellose sodium
- Polysorbate 20
- Silicified microcrystalline cellulose
- Magnesium stearate
- Polyvinyl alcohol
- Titanium dioxide

- Macrogol 3350
- Purified talc
- Iron oxide yellow
- Iron oxide red.

Supplier

JULUCA is supplied in Australia by:

ViiV Healthcare Pty Ltd
Level 4, 436 Johnston Street
Abbotsford, Victoria, 3067
Australia.

JULUCA: AUST R 291356

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