

JULUCA

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking JULUCA?

JULUCA contains the active ingredients dolutegravir and rilpivirine. JULUCA is used to treat human immunodeficiency virus (HIV) infection.

For more information, see Section [1. Why am I taking JULUCA?](#) in the full CMI.

2. What should I know before I take JULUCA?

Do not use if you have ever had an allergic reaction to JULUCA or any of the ingredients listed at the end of the CMI.

Do not use JULUCA if you are taking any of the following medicines: dofetilide, pilsicainide, fampridine, carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampicin, rifapentine, omeprazole,

esomeprazole, lansoprazole, pantoprazole, rabeprazole, dexamethasone and products containing St John's wort.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take JULUCA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with JULUCA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use JULUCA?

- The usual dosage of JULUCA is one tablet once a day with a meal.
- If you taken certain other medications this will affect when you can take JULUCA.
- Swallow the tablet whole with a glass of water.

More instructions can be found in Section [4. How do I take JULUCA?](#) in the full CMI.

5. What should I know while taking JULUCA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking JULUCA.• For as long as you are taking JULUCA your doctor will arrange for you to have regular blood tests to check for side effects.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly or change the dose without talking to your doctor.• Do not take this medicine to treat any other complaints.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how JULUCA affects you.• JULUCA may cause dizziness or make you feel less alert than normal.

Looking after your medicine	<ul style="list-style-type: none">• Store JULUCA in the bottle below 30°C.
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For more information, see Section [5. What should I know while taking JULUCA?](#) in the full CMI.

6. Are there any side effects?

Side effects that have been reported include headache, dizziness, nausea, vomiting, stomach pains or discomfort, diarrhoea, increased wind (flatulence), decreased appetite, weight gain, depression, anxiety, difficulty sleeping or falling asleep (insomnia), abnormal dreams, sleep disorders, fatigue, a lack of energy, feeling drowsy, itching, joint pain and muscle pain.

Serious side effects include allergic reactions, suicidal thoughts and behaviours and liver failure. Urgent medical attention is required.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

JULUCA

Active ingredient(s): *dolutegravir and rilpivirine (as hydrochloride)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using JULUCA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using JULUCA.**

Where to find information in this leaflet:

- [1. Why am I taking JULUCA?](#)
- [2. What should I know before I take JULUCA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take JULUCA?](#)
- [5. What should I know while taking JULUCA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking JULUCA?

JULUCA contains the active ingredients dolutegravir and rilpivirine.

Dolutegravir belongs to a group of antiretroviral medicines called integrase inhibitors (INIs). Rilpivirine belongs to a group of antiretroviral medicines called non-

nucleoside analogue reverse transcriptase inhibitors (NNRTIs).

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

JULUCA does not cure HIV infection however 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.

You can still pass on HIV when taking this medicine through sexual activity or through passing on blood or bodily secretions which carry the HIV virus, although the risk is lowered by taking antiretroviral therapy.

You should use proper precautions to prevent this from occurring. Discuss with your doctor the precautions needed to avoid infecting other people.

While taking JULUCA and/or any other therapy for HIV, you may continue to develop other infections and other complications of HIV infection. You should keep in regular contact with your doctor.

2. What should I know before I take JULUCA?

Warnings

Do not take JULUCA if:

- you are allergic to dolutegravir, rilpivirine or any of the ingredients listed at the end of this leaflet.

- Always check the ingredients to make sure you can use this medicine.
- you take any of the following medicines:
 - dofetilide or pilsicainide, used to treat heart conditions
 - fampridine, used to treat multiple sclerosis
 - carbamazepine, oxcarbazepine, phenobarbital, phenytoin, medicines known as anticonvulsants used to treat epilepsy and prevent seizures
 - rifampicin, rifapentine, medicines used to treat some bacterial infections such as tuberculosis
 - omeprazole, esomeprazole, lansoprazole, pantoprazole or rabeprazole, proton pump inhibitor medicines used to prevent and treat stomach ulcers, heartburn or acid reflux disease
 - dexamethasone, a corticosteroid medicine used in a variety of conditions such as inflammation and allergic reactions
 - products containing St John's Wort (*hypericum perforatum*), a herbal product used to treat depression

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor can discuss with you the benefits and risks of taking JULUCA whilst pregnant or breastfeeding.

It is important to use a reliable method of contraception to prevent pregnancy.

Taking dolutegravir (one of the components in JULUCA tablets) at the time of becoming pregnant or during the first 12 weeks of pregnancy may increase the risk of a type of birth defect known as neural tube defects such as spina bifida (a malformed spinal cord).

Women who are HIV positive should not breastfeed as HIV infection can be passed onto the baby through the breastmilk. Dolutegravir is known to pass into the breastmilk in small amounts.

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 and so the body starts to fight infections.

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

- old, hidden infections flaring up 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 medications to treat your HIV infection.

Symptoms may include:

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

If you get symptoms of infection or if you notice any of the symptoms above, tell your doctor immediately. Do not take other medicines for the infection without your doctor's advice.

3. What if I am taking other medicines?

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

Some medicines may interfere with JULUCA and affect how it works.

- metformin, a medicine used to treat diabetes
- medicines known as antacids which are used to treat indigestion and heartburn

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect JULUCA.

4. How do I take JULUCA?

How much to take

- The usual dosage of JULUCA is one tablet taken once a day with a meal.
- Follow the instructions provided and use JULUCA until your doctor tells you to stop.

When to take JULUCA

- Your doctor or pharmacist will tell you when to take JULUCA each day.

- If you take an antacid medicine to treat indigestion or heartburn, you must take JULUCA at least 4 hours before or 6 hours after you take the antacid.

Talk to your doctor or pharmacist for further advice on taking antacid medicines with JULUCA.

- If you take H₂-receptor antagonists to treat indigestion and heartburn (e.g. famotidine, cimetidine, nizatidine, ranitidine) you should take JULUCA at least 4 hours before or 12 hours after you take the H₂-receptor antagonist.
- If you take calcium or iron supplements, you must take JULUCA 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.
- If you take rifabutin to treat bacterial infections such as tuberculosis, you must also take a 25 mg dose of rilpivirine at the same time as you take JULUCA.

How to take JULUCA

- Swallow the tablet whole with a drink of water.
- It is important to take JULUCA with a meal. A protein-rich nutritional drink alone does not replace a meal.

If you forget to take JULUCA

JULUCA should be taken regularly at the same time each day.

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 JULUCA as you would normally.

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

If you take too much JULUCA

If you think that you have taken too much JULUCA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking JULUCA?

Things you should do

Ensure you have blood tests when you are meant to. It is important that your doctor monitors your health.

Tell your doctor straight away if you:

- become pregnant or intend to become pregnant
- have not taken JULUCA as intended

Remind any doctor, dentist or pharmacist you visit that you are taking JULUCA.

Things you should not do

- Do not stop using this medicine suddenly or change the dose.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.

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 everyday to stop your illness from getting worse. Because JULUCA does not cure HIV infections, you may still develop other infections and illnesses linked to HIV.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how JULUCA affects you.

JULUCA may cause dizziness or make you feel less alert than normal.

Looking after your medicine

Follow the instructions on the bottle on how to take care of your medicine properly.

Store it in a cool dry place (below 30°C) away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Within the first few weeks of treatment with anti-HIV medicines, some people, particularly those that have been HIV positive for some time, may develop inflammatory reactions (e.g. pain, redness, swelling, high temperature) which may resemble an infection and may be severe. It is thought that these reactions are caused by a recovery in the body's ability to fight infections, previously suppressed by HIV.

If you become concerned about any new symptoms, or any changes in your health after starting HIV treatment, discuss with your doctor immediately.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">● headache● dizziness● nausea and vomiting● stomach pains or discomfort● diarrhoea● increased wind (flatulence)● decreased appetite, weight gain● depression, anxiety● difficulty sleeping or difficulty falling asleep (insomnia)● abnormal dreams● sleep disorders● fatigue, lack of energy, feeling drowsy● itching	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • joint pain • muscle pain 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • swelling of the lips, tongue, wheezing or difficulty breathing, rash, hives on the skin. These are all signs of an allergic reaction • suicidal thoughts and behaviours (especially in patients who have had depression or mental health problems before) • liver failure, signs include yellowing of the skin and whites of the eyes or unusually dark urine 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Some side effects will only show up following a blood test. These include:

- inflammation in the liver
- increase in the level of liver enzymes

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

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What JULUCA contains

Active ingredient (main ingredients)	dolutegravir
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	rilpivirine (as hydrochloride)
Other ingredients (inactive ingredients)	croscarmellose sodium iron oxide red iron oxide yellow lactose monohydrate macrogol 3350 magnesium stearate mannitol microcrystalline cellulose polysorbate 20 polyvinyl alcohol povidone purified talc silicified microcrystalline cellulose sodium starch glycollate type A sodium stearyl fumarate titanium dioxide
Potential allergens	lactose monohydrate mannitol

Do not take this medicine if you are allergic to any of these ingredients.

What JULUCA looks like

JULUCA tablets are pink, film coated, oval, biconvex shaped debossed with "SV J3T" on one side.

JULUCA is available in bottles of 30 tablets. The bottle contains a desiccant. Once the bottle is opened, keep the desiccant in the bottle.

AUST R 291356

Who distributes JULUCA

ViiV Healthcare Pty Ltd

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Australia

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