ASO PRO

Juluca
dolutegravir 50 mg/
rilpivirine 25 mg tablets

JULUCA: AN OVERVIEW

A next step in HIV treatment for your adult clients who have been undetectable for at least six months.

2 medicines. 1 pill.

dolutegravir rilpivirine

JULUCA is a once-daily, complete HIV-1 regimen that may keep your clients undetectable* with 2 medicines in just 1 small pill.

Rodney†
Undetectable
since 2008

*Undetectable means keeping the amount of HIV-1 in the blood at very low levels (less than 50 copies per mL). Results may vary.
†Real patient diagnosed with HIV-1 and compensated for his time by ViiV Healthcare.
ASO Pro = AIDS Service Organization Professional.

INDICATION

JULUCA is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen for ≥6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of JULUCA. JULUCA should be taken with a meal

IMPORTANT SAFETY INFORMATION

Contraindications

- Do not use JULUCA in patients with previous hypersensitivity reaction to dolutegravir or rilpivirine
- Do not use JULUCA in patients receiving dofetilide, carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifapentine, systemic dexamethasone (>1 dose), St John's wort, and proton pump inhibitors (eg, esomeprazole, lansoprazole, omeprazole, pantoprazole, and rabeprazole)

Please see additional Important Safety Information throughout this brochure.
Please click here to see full Prescribing Information for JULUCA.

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Clinical trials.

Tested in	With more than	Evaluated at
2 Open-label* clinical trials	**1,000** Undetectable† adults	**48 & 100** Weeks

This study included two groups of patients, those who took JULUCA for 100 weeks and those who switched from their current stable regimen‡ to JULUCA at week 52.

Patients who entered these studies were undetectable† and on their current stable regimen for at least six months. They could not participate if they had liver problems or active hepatitis B, were likely to need treatment for hepatitis C during the trials, had failed a prior HIV treatment, or had suspected resistance to the components of JULUCA (dolutegravir or rilpivirine).

43 years was the median age of participants.

28% of participants were at least 50 years of age.

22% of participants were female.

The results are in.

In these studies, most people who were already undetectable† for at least six months stayed undetectable when they switched to JULUCA.§

AT 48 WEEKS

1 pill with 2 medicines was as effective at keeping people undetectable† as their previous 3- or 4-drug regimens.‡

95% of people who switched to JULUCA stayed undetectable†

95% of people who stayed on their current HIV regimen stayed undetectable†

AT 100 WEEKS‖

89% of people who took JULUCA for 100 weeks stayed undetectable†

93% of people who switched to JULUCA from week 52 to week 100 stayed undetectable†

*Both patients and their healthcare providers knew which medicines patients were taking.
†Undetectable means the amount of HIV-1 in the patients' blood was at very low levels (less than 50 copies per mL).
‡Regimens contained 2 nucleoside reverse transcriptase inhibitors (NRTIs) plus either an integrase strand transfer inhibitor (INSTI), a non-nucleoside reverse transcriptase inhibitor (NNRTI), or a protease inhibitor (PI).
§Results may vary.
‖Data on file, ViiV Healthcare group of companies, Research Triangle Park, NC.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions

Skin and Hypersensitivity Reactions:

- Hypersensitivity reactions have been reported with dolutegravir and were characterized by rash, constitutional findings, and sometimes organ dysfunction, including liver injury
- Severe skin and hypersensitivity reactions have been reported during postmarketing experience, including cases of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), with rilpivirine-containing regimens and have been accompanied by fever and/or organ dysfunctions, including elevations in hepatic serum biochemistries
- Discontinue JULUCA immediately if signs or symptoms of severe skin or hypersensitivity reactions develop, as a delay in stopping treatment may result in a life-threatening reaction. Clinical status, including liver aminotransferases, should be monitored and appropriate therapy initiated

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What can your clients expect?

Your clients may experience some side effects when switching medications.

Here's what people who participated in the clinical trials reported*:

SWITCHED TO JULUCA AT THE START OF THE TRIALS

	TAKING JULUCA	
Common Side Effects	Weeks 1-48	Weeks 1-100†
Diarrhea	2%	1%
Headache	2%	2%
Nausea†	1%	2%

CONTINUED CURRENT HIV REGIMEN AT THE START OF THE TRIALS

	TAKING CURRENT HIV REGIMEN	SWITCHED TO JULUCA
Common Side Effects	Weeks 1-48	Weeks 52-100†
Diarrhea	<1%	1%
Headache	0%	2%
Nausea†	0%	1%

SWITCHED TO JULUCA AT THE START OF THE TRIALS

	TAKING JULUCA	
Discontinuation	Weeks 1-48	Weeks 1-100†
People who left the study due to side effects	4%	7%

CONTINUED CURRENT HIV REGIMEN AT THE START OF THE TRIALS

	TAKING CURRENT HIV REGIMEN	SWITCHED TO JULUCA
Discontinuation	Weeks 1-48	Weeks 52-100†
People who left the study due to side effects	<1%	3%

Of the people who left the study due to side effects, the most common side effects leading to discontinuation were psychiatric disorders:

- 2% of patients who took JULUCA during weeks 1-48
- 2% of patients who took JULUCA during weeks 1-100†
- <1% of patients who continued their HIV regimens during weeks 1-48
- 1% of patients who switched to JULUCA during weeks 52-100†

Your clients should always talk to their doctor if they experience any side effects. Results may vary.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

*Results may vary.
†Data on file, ViiV Healthcare group of companies, Research Triangle Park, NC.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

Hepatotoxicity:

- Hepatic adverse events have been reported, including cases of hepatic toxicity (elevated serum liver biochemistries, hepatitis, and acute liver failure) in patients receiving a dolutegravir-containing regimen without pre-existing hepatic disease or other identifiable risk factors
- Patients with underlying hepatitis B or C or marked elevations in transaminases prior to treatment may be at increased risk for worsening or development of transaminase elevations with the use of JULUCA. In some cases, the elevations in transaminases were consistent with immune reconstitution syndrome or hepatitis B reactivation, particularly in the setting where anti-hepatitis therapy was withdrawn
- Monitoring for hepatotoxicity is recommended

Embryo-Fetal Toxicity:

- Assess the risks and benefits of JULUCA and discuss with the patient to determine if an alternative treatment should be considered at the time of conception through the first trimester of pregnancy due to the risk of neural tube defects
- Pregnancy testing is recommended before use of JULUCA. Individuals of childbearing potential should be counseled on the consistent use of effective contraception

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Evaluating bone mineral density.

A DEXA substudy* evaluated the change in BMD at 48 weeks following a switch to JULUCA from an HIV regimen containing tenofovir disoproxil fumarate (TDF). It compared patients who switched with patients who continued their TDF-containing regimens.

102 PATIENTS WERE INCLUDED

Switched to JULUCA
43 years was the median age of participants.
51% of participants were female.

Continued HIV regimen with TDF
46 years was the median age of participants.
53% of participants were female.

	MEAN CHANGE IN HIP BMD		MEAN CHANGE IN LUMBAR SPINE BMD	
	Patients	Week 48	Patients	Week 48
Switched to JULUCA	50	1.34%	52	1.46%
Continued HIV regimen with TDF	40	0.05%	42	0.15%

- Lumbar spine BMD declines of ≥5% were experienced by 2% of patients who switched to JULUCA and 5% of patients who continued their current TDF-containing regimens.

The long-term clinical significance of these BMD changes is unknown.

*Data on file, ViiV Healthcare group of companies, Research Triangle Park, NC.
Results may vary.
DEXA = dual-energy x-ray absorptiometry; scans were acquired using scanners that were calibrated longitudinally and centrally across sites.
BMD = bone mineral density.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

Depressive Disorders:
- Depressive disorders (including depressed mood, depression, dysphoria, major depression, mood altered, negative thoughts, suicide attempt, and suicidal ideation) have been reported with rilpivirine
- Promptly evaluate patients with severe depressive symptoms

Risk of Adverse Reactions or Loss of Virologic Response Due to Drug Interactions:
- The concomitant use of JULUCA and other drugs may result in known or potentially significant drug interactions (see Contraindications and Drug Interactions)
- Rilpivirine doses 3 and 12 times higher than the recommended dose can prolong the QTc interval. Consider alternatives to JULUCA when coadministered with a drug with a known risk of Torsade de Pointes. Consider the potential for drug interactions prior to and during therapy with JULUCA and monitor for adverse reactions

Please see additional Important Safety Information throughout this brochure.

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Taking JULUCA.

Understanding the "how" and "when" of taking JULUCA is important. Your clients should be sure to keep these considerations in mind:

Not actual pill size.

JULUCA should be taken every day with a meal — exactly as their doctor prescribes.

JULUCA should be taken around the same time every day (or night).

JULUCA is a replacement for your clients' current HIV regimens.

JULUCA should be taken exactly as prescribed.

Remember, it's important for your clients to keep their overall health in mind when considering HIV treatment options. Their doctor is a good source of information. Encourage clients to talk with their healthcare provider if they have questions.

Visit juluca.com to learn more.

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse reactions

The most common adverse reactions (incidence ≥2%, all Grades) with JULUCA were diarrhea (2%) and headache (2%)

Drug interactions

- Because JULUCA is a complete regimen, coadministration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended
- Coadministration of JULUCA with drugs that induce or inhibit UGT1A1 and/or CYP3A may affect plasma concentrations
- Drugs that increase gastric pH may decrease plasma concentrations of the components of JULUCA
- Consider alternatives to prescribing JULUCA with drugs with a known risk of Torsade de Pointes
- When coadministering JULUCA with rifabutin, take an additional 25 mg tablet of rilpivirine with JULUCA once daily with a meal
- Administer JULUCA 4 hours before or 6 hours after taking antacids, polyvalent cation-containing products or laxatives, sucralfate, oral supplements containing iron or calcium, or buffered medications
- Consult the full Prescribing Information for JULUCA for more information on potentially significant drug interactions, including clinical comments

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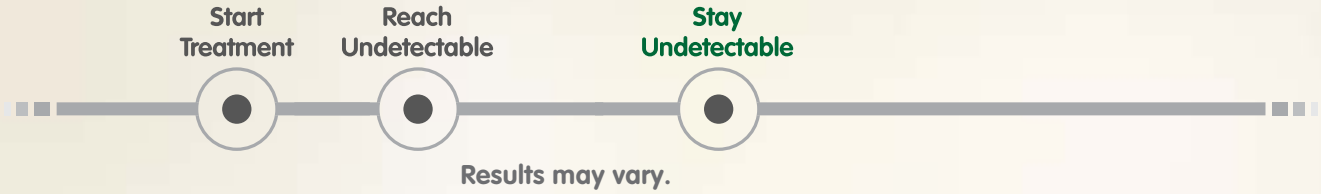
Now that your client is undetectable,* have they thought about what's next?

Reaching undetectable is a major milestone, and it's important for your clients to stay on top of their treatment.



There are many HIV treatment options available. Does your client know how many medicines are in their HIV regimen?

Starting the conversation about JULUCA.

Encourage your clients to talk to their doctor about JULUCA— and find out if it could be a next step for them.

A full Doctor Discussion Guide can be downloaded at juluca.com

*Undetectable for at least six months. Undetectable means keeping the amount of HIV-1 in the blood at very low levels (less than 50 copies per mL).

IMPORTANT SAFETY INFORMATION (cont'd)

Use in specific populations

- **Pregnancy:** There are insufficient human data on the use of JULUCA during pregnancy to definitively assess a drug-associated risk for birth defects and miscarriage. An Antiretroviral Pregnancy Registry has been established. Advise individuals of childbearing potential of the potential risk of neural tube defects. Assess the risks and benefits of JULUCA and discuss with the patient to determine if an alternative treatment should be considered at the time of conception through the first trimester of pregnancy or if pregnancy is confirmed in the first trimester
- **Rilpivirine Exposure During Pregnancy:** Total rilpivirine exposures were generally lower during pregnancy compared with the postpartum period
- **Lactation:** Breastfeeding is not recommended due to the potential for HIV-1 transmission, developing viral resistance in HIV-positive infants, and adverse reactions in a breastfed infant
- **Females and Males of Reproductive Potential:** Pregnancy testing is recommended before initiation of JULUCA. Counsel individuals of childbearing potential taking JULUCA on the consistent use of effective contraception

Please see additional Important Safety Information throughout this brochure.

Please click here to see full Prescribing Information for JULUCA.

ViiVConnect

Comprehensive patient support programs and resources for healthcare providers

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Call to speak to an Access Coordinator

1-844-588-3288 (toll-free)
Monday-Friday, 8AM-11PM (ET)

Get support from ViiVConnect

LEARN MORE

[a]Subject to eligibility and program terms and conditions; ViiVConnect programs do not constitute health insurance.