

# iMedix: Your Personal Health Advisor.

## Juluca

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## Description

Side Effects Headache or diarrhea may occur. If either of these effects lasts or gets worse, tell your doctor or pharmacist promptly. Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. As your immune system gets stronger, it can begin to fight off infections you already had, possibly causing disease symptoms to come back. You could also have symptoms if your immune system becomes overactive. This reaction may happen at any time (soon after starting HIV treatment or many months later). Get medical help right away if you have any serious symptoms, including: unexplained weight loss, severe tiredness, muscle aches/weakness that doesn't go away, headaches that are severe or don't go away, joint pain, numbness/tingling of the hands/feet/arms/legs, vision changes, signs of infection (such as fever, chills, swollen lymph nodes, trouble breathing, cough, non-healing skin sores), signs of an overactive thyroid (such as irritability, nervousness, heat intolerance, fast/pounding/irregular heartbeat, bulging eyes, unusual growth in the neck/thyroid known as a goiter), signs of a certain nerve problem known as Guillain-Barre syndrome (such as unsteadiness, loss of coordination, trouble swallowing/speaking/chewing, trouble moving your eyes), signs of liver disease (such as nausea/vomiting that doesn't stop, loss of appetite, stomach/abdominal pain, yellowing eyes/skin, dark urine). Tell your doctor right away if you have any serious side effects, including: mental/mood changes (such as depression, thoughts of suicide). Changes in body fat may occur while you are taking this medication (such as increased fat in the upper back and stomach areas, decreased fat in the arms and legs). The cause and long-term effects of these changes are unknown. Discuss the risks and benefits of treatment with your doctor, as well as the possible use of exercise to reduce this side effect. Rilpivirine can commonly cause a rash that is usually not serious. However, you may not be able to tell it apart from a rare rash that could be a sign of a severe reaction. Get medical help right away if you develop any rash. A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US – Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at [www.fda.gov/medwatch](http://www.fda.gov/medwatch). In Canada – Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345. Uses Dolutegravir/rilpivirine is used to help control HIV infection. It helps to decrease the amount of HIV in your body so your immune system can work better. This

lowers your chance of getting HIV complications (such as new infections, cancer) and improves your quality of life. Dolutegravir is an integrase inhibitor while rilpivirine is a non-nucleoside reverse transcriptase inhibitor (NNRTI). Both drugs block the virus from growing and infecting more cells. Dolutegravir/rilpivirine is not a cure for HIV infection. To decrease your risk of spreading HIV disease to others, continue to take all HIV medications exactly as prescribed by your doctor. Use an effective barrier method (latex or polyurethane condoms/dental dams) during sexual activity as directed by your doctor. Do not share personal items (such as needles/syringes, toothbrushes, and razors) that may have contacted blood or other body fluids. Consult your doctor or pharmacist for more details. How to use Juluca Read the Patient Information Leaflet if available from your pharmacist before you start using dolutegravir/rilpivirine and each time you get a refill. If you have any questions, ask your doctor or pharmacist. Take this medication by mouth with a meal as directed by your doctor, usually once daily. The dosage may be based on other medications you are taking. Be sure to tell your doctor and pharmacist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). Medications which reduce or block stomach acid (such as proton pump inhibitors/PPIs, H2 blockers, antacids) may reduce the absorption of rilpivirine, making this product work less well. Do not take PPIs (such as omeprazole, lansoprazole) while using this medication. If you take antacids, take the antacids at least 6 hours before or at least 4 hours after this product. If you take H2 blockers (such as famotidine, ranitidine), take them at least 12 hours before or at least 4 hours after this product. Sucralfate and products containing aluminum or magnesium (such as antacids, laxatives, buffered medications) may reduce the absorption of dolutegravir, making this product work less well. Take these products 6 hours before or 4 hours after this medication. Calcium or iron supplements (including vitamins/minerals that contain calcium or iron) may also reduce the absorption of dolutegravir, making this product work less well. Take these products 6 hours before or 4 hours after this medication. Or you can take this medication and the calcium or iron supplements together at the same time with a meal. It is very important to keep taking this medication exactly as prescribed by your doctor. Do not skip any doses. For the best effect, take this medication at evenly spaced times. To help you remember, take this medication at the same time every day. Do not take more or less of this drug than prescribed or stop taking it even for a short time unless directed to do so by your doctor. Doing so may cause the amount of virus to increase, make the infection more difficult to treat (resistant), or worsen side effects. Precautions Before taking this product, tell your doctor or pharmacist if you are allergic to dolutegravir or rilpivirine; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney disease, liver disease (such as hepatitis B, hepatitis C), mental/mood disorders (such as depression). Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). Before using this medication, women of childbearing age should talk with their doctor(s) about the risks and benefits. Tell your doctor if you are pregnant or if you plan to become pregnant. Your doctor should direct you to get a pregnancy test before starting this medication. During pregnancy, this medication should be used only when clearly needed. It is not recommended for use during the first trimester of pregnancy due to possible harm to the unborn baby. Ask about reliable forms of birth control while using this medication. Dolutegravir and rilpivirine pass into breast milk. Because breast milk can transmit HIV, do not breast-feed. Interactions Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval. Some products that may interact with this drug are: dofetilide, orlistat, proton pump inhibitors (PPIs such as esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole). Do not take this medication with other products that treat HIV infection. Do not take this medication with other products that contain rilpivirine, unless you are also taking rifabutin. Other medications can affect the removal of rilpivirine from your body, which may affect how rilpivirine works. Examples include dexamethasone, certain macrolide antibiotics (such as amoxil, zithromax, flagyl, levofloxacin, ciprofloxacin), rifamycins (such as rifampin, rifapentine), St. John's wort, certain drugs used to treat seizures (such as carbamazepine, oxcarbazepine, phenobarbital, phenytoin, primidone), a certain combination product used to treat chronic hepatitis C (ombitasvir/paritaprevir/ritonavir/dasabuvir), among others. Overdose If someone has overdosed and has

serious symptoms such as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include: fast/irregular heartbeat, severe dizziness, fainting. Do not share this medication with others. Lab and/or medical tests (such as viral load, T-cell counts, liver function) should be done while you are taking this medication. Keep all medical and lab appointments. Consult your doctor for more details. If you miss a dose, take it with a meal as soon as you remember. If it is near the time of the next dose, skip the missed dose. Take your next dose at the regular time. Do not double the dose to catch up. Store at room temperature away from light and moisture. Store this drug in its original bottle with the desiccant inside the bottle. Do not store in the bathroom. Keep all medications away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

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## Side Effects

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## Uses

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## Interactions

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## Other Details

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