Juluca

WHAT IS JULUCA?

Juluca is a complete HIV regimen used as part of antiretroviral therapy (ART). Juluca contains two antiretroviral drugs (ARVs) combined in one tablet:

- dolutegravir (DTG, Tivicay)
- rilpivirine (RPV, Edurant)

The FDA approved Juluca in 2017 as an ARV for people with HIV infection. Juluca is manufactured by ViiV Healthcare.

One of the drugs in Juluca, dolutegravir, is a type of drug called an integrase inhibitor. Integrase inhibitors block integrase (an HIV enzyme). HIV uses integrase to insert (integrate) its viral DNA into the DNA of host CD4 cells. Blocking integrase prevents HIV from replicating. The other drug, rilpivirine, is a non-nucleoside reverse transcriptase inhibitor (NNRTI). NNRTIs bind to and block reverse transcriptase (an HIV enzyme). HIV uses reverse transcriptase to convert its RNA into DNA (reverse transcription). Blocking reverse transcriptase and reverse transcription prevents HIV from replicating.

When used alone as a complete regimen to treat HIV infection, Juluca may help:

- Reduce the amount of HIV in your blood. This is called viral load.
- Increase the number of CD4 cells in your blood that help fight off other infections.

Reducing the amount of HIV and increasing CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting opportunistic infections (OIs) that can happen when your immune system is weak. Read more about viral suppression.

Juluca does not cure HIV infection or AIDS. You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

WHO SHOULD TAKE JULUCA?

Juluca is a two-drug fixed-dose combination medication that is used alone as a complete regimen to treat HIV infection in adults to replace their current HIV medicines when their healthcare provider determines that they meet certain requirements.

The safety and effectiveness of Juluca has not been established in children under 18 years of age. Juluca has not been carefully studied in the elderly (65 years of age and older).

All people with HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. Read more about U.S. ART guidelines.

Juluca provides two drugs in one pill. It can be more convenient to use Juluca than some other combinations of drugs that must be taken separately or at different times of the day. This could mean fewer missed doses and better control of HIV. **Juluca is used as a complete regimen for the treatment of HIV infection.**

WHO SHOULD NOT TAKE JULUCA?

Do not take Juluca if you are allergic to dolutegravir, rilpivirine, or any of the ingredients in this drug.

Do not take Juluca if you are taking any of the following medicines. Taking Juluca with these medicines may affect how Juluca works. Juluca may cause serious or life-threatening side effects or death when used with these medicines:

- Seizure medicines: carbamazepine, oxcarbazepine, phenobarbital, phenytoin
- Tuberculosis (TB) medicines: rifampin, rifapentine
- Heart medicine: dofetilide
- Herbal product: St. John's Wort (*Hypericum perforatum*)
- Proton pump inhibitor (PPI) medicines for stomach/intestinal problems: esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole
- Steroid medicine dexamethasone (more than a single dose)

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. If you have taken any of these medicines in the past four weeks, talk to your healthcare provider or pharmacist before starting treatment with Juluca.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING JULUCA?

Before you take Juluca, tell your healthcare provider about all of your medical conditions, and in particular if you:

- Have ever had a severe skin rash or an allergic reaction to medicines that contain dolutegravir or rilpivirine
- Have or have had liver problems, including hepatitis B virus (HBV) or hepatitis C virus (HCV) infection
- Have ever had a mental health problem

Talk to your healthcare provider if you are pregnant, you plan to become pregnant, you become pregnant, or think you may be pregnant during treatment with Juluca. Your healthcare provider may prescribe a different medicine than Juluca if you are planning to become pregnant or if pregnancy is confirmed during the first 12 weeks of pregnancy. If you can become pregnant, your healthcare provider will perform a pregnancy test before you start treatment with Juluca and you should consistently use effective birth control (contraception) during treatment with Juluca.

There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry. Read more about pregnancy and HIV.

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with Juluca. It is not known if Juluca can pass to your baby in your breastmilk. Do not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your healthcare provider about the best way to feed your baby.

WHAT ABOUT DRUG RESISTANCE?

Many new copies of HIV are mutations. These new copies are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called developing resistance to the drug. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. Read more about HIV drug resistance.

Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.

HOW IS JULUCA TAKEN?

Juluca is taken by mouth as a tablet. Each Juluca tablet contains 50 mg of dolutegravir and 25 mg of rilpivirine. The recommended dosage of Juluca for adults is one tablet once daily.

Take Juluca at the same time each day with food. Taking Juluca with food is important to help get the right amount of medicine in your body. A protein drink does not replace food.

If you take antacids, laxatives, or other products that contain aluminum, calcium carbonate, magnesium, or buffered medicines, Juluca should be taken at least 4 hours before or 6 hours after you take these medicines.

If you need to take iron or calcium supplements, including multivitamins that contain iron or calcium, by mouth during treatment with Juluca you may take these supplements at the same time that you take Juluca with food. If you do not take these supplements with Juluca and food, take Juluca at least 4 hours before or 6 hours after you take these supplements.

WHAT ARE THE SIDE EFFECTS?

When you start any ARV, you may have temporary side effects such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of Juluca are diarrhea and headaches.

Juluca can cause serious side effects including:

Severe skin rash and allergic reactions. Call your healthcare provider right away if you develop a rash with Juluca. Stop taking Juluca and get medical help right away if you develop a rash with any of the following signs or symptoms:

- Fever
- Generally ill feeling
- Tiredness
- Muscle or joint aches
- Blisters or sores in mouth
- Blisters or peeling of the skin
- Redness or swelling of the eyes
- Swelling of the mouth, face, lips, or tongue
- Problems breathing

Liver problems. People with a history of HBV or HCV who have certain liver test function changes may have an increased risk

of developing new or worsening changes in certain liver tests during treatment with Juluca. Liver problems, including liver failure, have also happened in people without a history of liver disease or other risk factors. Your healthcare provider may do blood tests to check your liver function. Tell your healthcare provider right away if you get any of the following signs or symptoms of liver problems:

- Your skin or the white part of your eyes turns yellow (jaundice)
- Dark or "tea-colored" urine
- Light-colored stools (bowel movements)
- Loss of appetite for several days or longer
- Nausea or vomiting
- Pain, aching, or tenderness on the right side of your stomach area

Depression or mood changes. Tell your healthcare provider right away or get medical help if you have any of the following symptoms:

- Feeling sad or hopeless
- Feeling anxious or restless
- Have thoughts of hurting yourself (suicide) or have tried to hurt yourself

These are not all the possible side effects of Juluca. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

HOW DOES JULUCA REACT WITH OTHER DRUGS?

All ARVs can interact with other drugs or supplements you are taking. These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take Juluca with other medicines.

See above for a list of medications that should not be taken with Juluca.

Juluca is a complete regimen for the treatment of HIV infection; therefore, taking Juluca with other ARVs for the treatment of HIV infection is not recommended.

MORE INFORMATION

Visit the Juluca website.

Visit the Juluca healthcare professional website.

Download the full Prescribing Information.

Download the Patient Information leaflet.

Download the Doctor Discussion Guide to bring to your next medical appointment.

Check out the ViiV Healthcare Patient Assistance Program.

Get a ViiV Healthcare Savings Card.

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