

## Talk to your doctor about JULUCA.

JULUCA is a prescription medicine that is used without other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults to replace their current anti-HIV-1 medicines when their healthcare provider determines that they meet certain requirements. HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS). It is not known if JULUCA is safe and effective in children.

To find out if JULUCA may be a next step for you, here's a list of questions:

### Questions to ask yourself:

1. **My current HIV treatment is:**  
 1 pill each day     2 pills each day  
 more than 2 pills each day
2. **My HIV treatment gets in the way of the rest of my life:**  
 not at all     several times a week  
 every day
3. **I have side effects:**  
 never     sometimes     often
4. **I'm undetectable\*—a once-daily pill with fewer medicines could fit my lifestyle:**  
 yes     no
5. **I'm concerned about the effects my HIV medicines may be having on my body:**  
 not at all     sometimes     often

### Questions to ask your HIV healthcare team:

1. **I've heard about JULUCA. What are its benefits and risks?**
2. **I'm undetectable\* now. Is there a reason to consider switching to JULUCA?**
3. **How many medicines are in my current HIV regimen?**
4. **How might JULUCA fit in with my health goals?**

#### Notes:

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

### IMPORTANT SAFETY INFORMATION

#### Do not take JULUCA if you:

- have ever had an allergic reaction to a medicine that contains dolutegravir or rilpivirine.
- are taking any of the following medicines:
  - dofetilide
  - carbamazepine
  - oxcarbazepine
  - phenobarbital
  - phenytoin
  - rifampin
  - rifapentine
  - proton pump inhibitors (including esomeprazole, lansoprazole, omeprazole, pantoprazole sodium, rabeprazole)
  - St. John's wort (*Hypericum perforatum*)
  - more than 1 dose of the steroid medicine dexamethasone or dexamethasone sodium phosphate

#### What are the possible side effects of JULUCA?

#### 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

## IMPORTANT SAFETY INFORMATION (cont'd)

### What are the possible side effects of JULUCA? (cont'd)

#### JULUCA can cause serious side effects, including: (cont'd)

- **Liver problems.** People with a history of hepatitis B or C virus who have certain liver function test 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 history of liver disease or other risk factors. Your healthcare provider may do blood tests to check your liver function. **Call your healthcare provider right away if you develop 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)
  - nausea or vomiting
  - loss of appetite
  - 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
- **The most common side effects of JULUCA include:**
  - diarrhea
  - headache

These are not all the possible side effects of JULUCA. For more information, ask your healthcare provider or pharmacist. Tell your healthcare provider right away if you have any new symptoms while taking JULUCA.

#### Before you take JULUCA, tell your healthcare provider 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 or C infection.
- have ever had a mental health problem.
- are pregnant or plan to become pregnant. One of the medicines in JULUCA, called dolutegravir, may harm your unborn baby.
  - **You should not take JULUCA at the time of becoming pregnant or during the first 12 weeks of pregnancy.** Your healthcare provider may change your medicine during this time in your 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
  - Tell your healthcare provider right away if you are planning to become pregnant, you become pregnant, or think you may be pregnant during treatment with JULUCA
- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take JULUCA.** You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby. It is not known if JULUCA can pass to your baby in your breast milk.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medicines interact with JULUCA. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with JULUCA.
- Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take JULUCA with other medicines.

#### How to take JULUCA?

- **Take JULUCA 1 time a day exactly as your healthcare provider tells you.**
- **Always take JULUCA with a meal.** A protein drink alone does not replace a meal.

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

Please read the [Important Facts](#) about JULUCA on page 3 and discuss it with your healthcare provider.

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Phone: 1-844-588-3288 (toll-free)  
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Please see additional Important Safety Information for JULUCA on page 1.  
Please see [Important Facts](#) about JULUCA on page 3.

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## IMPORTANT FACTS

This is only a brief summary of important information about JULUCA and does not replace talking to your healthcare provider about your condition and treatment.

(Jah-LOO-kah)

### ABOUT JULUCA

- JULUCA is a prescription medicine that is used without other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults to replace their current anti-HIV-1 medicines when their healthcare provider determines that they meet certain requirements.
- HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).
- It is not known if JULUCA is safe and effective in children.

### HOW TO TAKE JULUCA

- **Take JULUCA 1 time a day exactly as your healthcare provider tells you.**
- **Always take JULUCA with a meal.** A protein drink alone does not replace a meal.

### DO NOT TAKE JULUCA IF YOU

- have ever had an allergic reaction to a medicine that contains dolutegravir or rilpivirine.
- are taking any of the following medicines: dofetilide; carbamazepine; oxcarbazepine; phenobarbital; phenytoin; rifampin; rifapentine; proton pump inhibitors (including esomeprazole, lansoprazole, omeprazole, pantoprazole sodium, rabeprazole); St. John's wort (*Hypericum perforatum*); or more than 1 dose of the steroid medicine dexamethasone or dexamethasone sodium phosphate.

### BEFORE TAKING JULUCA

#### Tell your healthcare provider 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 or C infection.
- have ever had a mental health problem.
- are pregnant or plan to become pregnant. One of the medicines in JULUCA, called dolutegravir, may harm your unborn baby.
  - **You should not take JULUCA at the time of becoming pregnant or during the first 12 weeks of pregnancy.** Your healthcare provider may change your medicine during this time in your 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.
  - Tell your healthcare provider right away if you are planning to become pregnant, you become pregnant, or think you may be pregnant during treatment with JULUCA.
- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take JULUCA.** You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby. It is not known if JULUCA can pass to your baby in your breast milk. Talk with your healthcare provider about the best way to feed your baby.

### BEFORE TAKING JULUCA (cont'd)

#### Tell your healthcare provider about all the medicines you take:

- Keep a list that includes all prescription and over-the-counter medicines, vitamins, and herbal supplements, and show it to your healthcare provider and pharmacist.
- Ask your healthcare provider or pharmacist about medicines that should not be taken with JULUCA.
- Do not start taking a new medicine without telling your healthcare provider.

### POSSIBLE SIDE EFFECTS OF JULUCA

#### 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 hepatitis B or C virus who have certain liver function test 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 history of liver disease or other risk factors. Your healthcare provider may do blood tests to check your liver function. **Call your healthcare provider right away if you develop 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); nausea or vomiting; loss of appetite; 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.
- **The most common side effects of JULUCA include:** diarrhea and headache.

These are not all the possible side effects of JULUCA. Tell your healthcare provider right away if you have any new symptoms while taking JULUCA. You may report side effects to FDA at 1-800-FDA-1088.

### GET MORE INFORMATION

- This is only a brief summary of important information about JULUCA. Talk to your healthcare provider or pharmacist to learn more.
- Go to JULUCA.com or call 1-877-844-8872, where you can also get FDA-approved labeling.



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