Juluca (dolutegravir, rilpivirine)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Juluca
- **Generic name:** Dolutegravir, rilpivirine
- **Pharmacological class:** HIV-1 integrase strand transfer inhibitor (INSTI) + non-nucleoside reverse transcriptase inhibitor
- **Strength and Formulation:** 50mg/25mg; tabs
- **Manufacturer:** ViiV Healthcare
- **How supplied:** Tabs—30
- **Legal Classification:** Rx

Juluca


NDC 49702-242-13
Rx Only
Juluca
(dolutegravir and rilpivirine)
Tablets
50 mg/25 mg
Note to pharmacist:
Do not cover ALERT box with pharmacy label.
ALERT: Find out about medicines that should NOT be taken with JULUCA.
30 tablets

Indications

- A complete regimen for the treatment of **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

Dosage & Administration

- Take with a meal
- 1 tab once daily
- Concomitant rifabutin: take additional rilpivirine 25mg tab once daily during coadministration

Considerations for Special Populations

- **Pediatric:** Not established
- **Pregnancy:** Insufficient data to adequately assess risk
- **Nursing mothers:** Not recommended
- **Elderly:** Insufficient number of patients studied
- **Renal impairment:** Severe renal impairment (CrCl <30mL/min) or ESRD: increase monitoring

Contraindications

- Concomitant dofetilide, carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifapentine, systemic dexamethasone (more than a single dose), St. John's wort, esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole

Warnings/Precautions

- **Discontinue immediately** if severe skin or hypersensitivity reactions develop; monitor
- **Increased risk** for worsening/ development of elevated transaminases in patients with underlying hepatitis B or C; monitor for hepatotoxicity
- Promptly evaluate if depressive symptoms occur

Interactions

- See **Contraindications**
- Concomitant other HIV-1 antiretroviral therapy: not recommended
- May be affected by drugs that induce or inhibit UGT1A1, UGT1A3, UGT1A9, BCRP, and P-gp enzymes or transporters
- May be **antagonized** by CYP3A inducers
- May be **potentiated** by CYP3A inhibitors

Interactions

- Concomitant drugs with a known risk of Torsade de pointes: consider alternatives
- May potentiate drugs eliminated via OCT2 or MATE1
- Drugs that increase **gastric pH** may result in decreased plasma concentration
- Concomitant antacids, cation-containing products, laxatives, sucralfate, oral iron/calcium supplements, and buffered drugs: give Juluca 4hrs before or 6hrs after

Interactions

- Separate H_2-receptor antagonists by at least 4hrs before or 12hrs after
- Limit concomitant **metformin** dose to 1000mg/day; adjust metformin dose when starting or stopping Juluca; monitor closely
- May be **potentiated** by clarithromycin, erythromycin, telithromycin; consider alternatives (eg, azithromycin)
- Concomitant methadone; monitor

Adverse Reactions

- Diarrhea
- Headache
- Insomnia
- Fatigue
- Immune reconstitution syndrome
- Lab abnormalities
- Hypersensitivity reactions
- DRESS
- Hepatotoxicity
- Depressive disorders

Mechanism of Action

- **Dolutegravir** inhibits HIV integrase by binding to the integrase active site and blocking the strand transfer step of retroviral DNA integration which is essential for the HIV replication cycle
- **Rilpivirine** inhibits HIV-1 replication by non-competitive inhibition of HIV-1 reverse transcriptase

Clinical Studies

- The efficacy of Juluca was evaluated in two 148-week Phase 3, randomized, multicenter, parallel-group, open-label, controlled non-inferiority trials **(SWORD-1** and **SWORD-2)** in virologically suppressed patients switching from their current antiretroviral regimen to dolutegravir + rilpivirine (N=1,024)

Clinical Studies

- Study patients were randomized to continue their current antiretroviral regimen or be switched to dolutegravir + rilpivirine given once dail**y**
- **Primary efficacy endpoint** was the proportion of patients with HIV-1 RNA <50 copies/mL at Week 48

Clinical Studies

- Pooled virologic outcomes showed **95%** of patients in the dolutegravir + rilpivirine group and **95%** in the current regimen group achieved HIV-1 RNA <50 copies/mL at Week 48
  - Treatment difference -0.2% (95% CI: -3.0%, 2.5%)

Clinical Studies

- The proportion of patients with HIV-1 RNA ≥50 copies/mL was **<1%** in the dolutegravir + rilpivirine group vs **1%** in the current regimen group
  - Treatment difference -0.6% (95% CI: -1.7%, 0.6%)
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/juluca/drug/34773/