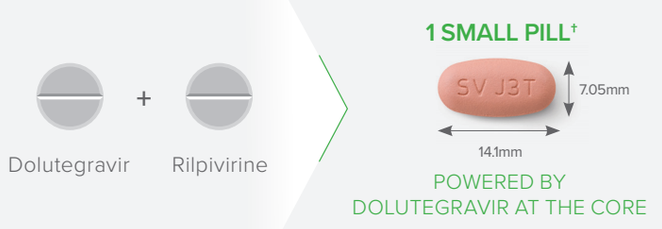
Juluca dolutegravir/rilpivirine FAST FACTS

INDICATION

For the treatment of HIV-1 infection in adults who are virologically-suppressed on a stable antiretroviral regimen for at least 6 months with no history of virological failure and no known or suspected resistance to any NNRTI or INI[1]

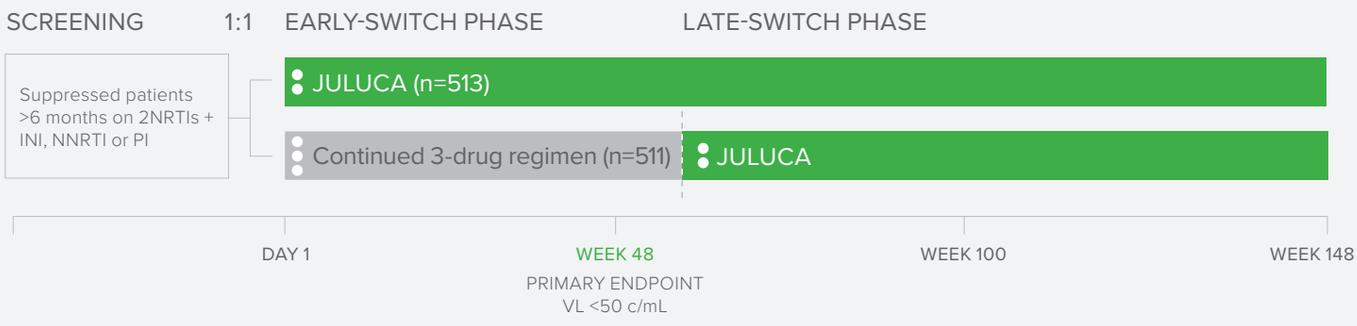
THE FIRST 2-DRUG REGIMEN IN A SINGLE PILL



†Pill is for indicative purposes only and is not to exact size

SWORD-1 AND SWORD-2 PHASE III STUDIES SUPPORTING JULUCA

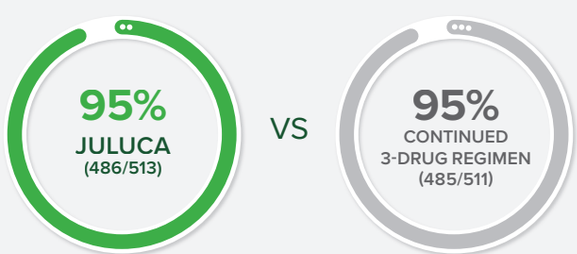
Two large, open-label studies with over 1,000 patients in total[2]



In these studies supporting JULUCA, DTG 50 mg and rilpivirine 25 mg were used. Bioequivalence has been demonstrated

- Patients who switched to JULUCA had a median time on ART of 4.25 years[2]
- 87% of subjects were new to both DTG and RPV[4]

JULUCA – non-inferior to continued 3-drug regimens in maintaining virological suppression at 48 Weeks[2]



Similar rates of AEs in both arms (77% vs 71%)[2]

Few drug-related AEs resulted in discontinuation (JULUCA: 4% vs continued 3-drug regimens: <1%)[2]

Adverse events reported in ≥5% of subjects in the JULUCA arm: psychiatric disorders (12%), nasopharyngitis (10%), headache (8%) and diarrhoea (6%)[2]

0 failures WITH RESISTANCE TO DTG AT 48 WEEKS[2]

A 2-drug regimen may reduce ARV exposure and potential associated toxicities

3 → 2

2 WELL-TOLERATED AGENTS, IN 1 PILL

Statistically significant recovery in bone mineral density (DEXA sub-study)[3]

Maintains lipid levels[2]

KEY DRUG INTERACTIONS

Contraindicated:[1]

Proton pump inhibitors • Dofetilide • Rifampicin, rifapentine • Carbamazepine, oxcarbazepine, phenobarbital, phenytoin • Systemic dexamethasone • St John's wort

Dose separation for H_2-antagonists either 12 hours before or 4 hours after taking JULUCA[1]

Dose separation for antacids either 6 hours before or 4 hours after taking JULUCA[1]

Metformin dose monitoring or adjustment[1]

Please consult the SmPC before prescribing

HOW TO Rx

JULUCA

One tablet

Once a day

Taken with a meal

Juluca▼
dolutegravir/rilpivirine

PRESCRIBING INFORMATION

Juluca▼ dolutegravir 50mg/rilpivirine 25mg tablets

See Summary of Product Characteristics (SmPC) before prescribing

Indication: HIV-1 in virologically suppressed adults (HIV-1 RNA <50 copies/mL) on stable ART for at least 6 months with no history of virological failure and no known resistance to any NNRTI or INI. **Dosing:** *Adults (over 18 years):* one tablet once daily **with food.** *Elderly:* Limited data in 65+ yrs. Caution in severe hepatic or renal impairment. **Contraindications:** Hypersensitivity to any ingredient. Co-administration with dofetilide, carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampicin, rifapentine, proton pump inhibitors, systemic dexamethasone (excluding single dose) or St John's Wort. **Warnings/precautions:** Risk of hypersensitivity reactions. Discontinue Juluca immediately if suspected. Risks of prolongation of QTc interval, osteonecrosis, opportunistic infections. Monitor LFTs in Hepatitis B/C co-infection and ensure effective Hepatitis B therapy. Small rise in serum creatinine in first 4 weeks of treatment, not considered clinically relevant. Do not co-administer with other antiretrovirals (except in case of co-administration of rifabutin, when an extra dose of rilpivirine 25mg should be used). Use with antacids or once-daily H_2-receptor antagonists requires dosage separation. Calcium, iron or multivitamins should be taken at the same time as Juluca with food, otherwise dosage separation recommended. Caution with metformin: monitor renal function and consider metformin dose adjustment to minimise risk of lactic acidosis. If macrolide antibiotics are required, consider azithromycin. Caution with antimalarials (artemether/lumefantrine) or anticoagulants (dabigatran). **Pregnancy/lactation:** Not recommended. Avoid breast-feeding. **Side effects:** See SmPC for full details. Increased total and LDL cholesterol, insomnia, headache, dizziness, nausea, diarrhoea, increased triglycerides, decreased appetite, abnormal dreams, depression, anxiety, sleep disorders, GI disorders, rash, pruritus, fatigue, decreased white blood cell count, haemoglobin and platelet count, arthralgia, myalgia, hypersensitivity, hepatitis, suicidal ideation or suicide attempt, acute hepatic failure. Changes in laboratory biochemistries: elevations of ALT, AST, pancreatic amylase, bilirubin and CPK. **Basic NHS costs:** £699.02 for 30 tablets (EU/1/18/1282/001). MA holder: ViiV Healthcare UK Ltd, 980 Great West Road, Brentford, Middlesex TW8 9GS. Further information available from Customer Contact Centre, GlaxoSmithKline UK Ltd, Stockley Park West, Uxbridge, Middlesex UB11 1BT.

POM S1A

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Zinc code: UK/DTGRPV/0030/18

Adverse events should be reported. For the UK, reporting forms and information can be found at ***www.mhra.gov.uk/yellowcard*** or search for **MHRA Yellowcard** in the **Google Play** or **Apple App store**. Adverse events should also be reported to GlaxoSmithKline on 0800 221441.

Adverse events should be reported. For Ireland, adverse events should be reported directly to the HPRA; Freepost, Pharmacovigilance Section, Health Products Regulatory Authority, Earlsfort Terrace, Dublin 2, Tel: +353 1 676 4971, ***medsafety@hpra.ie.*** Adverse events should also be reported to GlaxoSmithKline on 1800 244 255.

REFERENCES

1. JULUCA▼ (dolutegravir/rilpivirine) Summary of Product Characteristics. Available from; www.medicines.org.uk, accessed on May 2018.
2. Llibre JM *et al. Lancet* 2018; 391: 839–49.
3. McComsey G *et al. AIDS* 2018; 32: 477–485.
4. Oglesby *et al.* Presented at: 16th European AIDS Conference; October 25–27, 2017; Milan, Italy. Poster BPD1/2.

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