

## Prescribing Information

### Juluca<sup>▼</sup> 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, immune reactivation syndrome. 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<sub>2</sub>-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 during pregnancy. Before

initiating Juluca, women of childbearing

potential (WOCBP) should undergo pregnancy

testing. WOCBP who are taking Juluca should

use effective contraception. 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

Trade marks are owned by or licensed to the ViiV Healthcare group of companies.

Date of approval: January 2019

Zinc code: UK/DTGRPV/0030/18(2)

Adverse events should be reported. For the UK, reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://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](mailto:medsafety@hpra.ie). Adverse events should also be reported to GlaxoSmithKline on 1800 244 255.