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, 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_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 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 BV, Huis ter Heideweg 62, 3705 LZ Zeist, Netherlands. Further information available from Customer Contact Centre, GlaxoSmithKline UK Ltd, Stockley Park West, Uxbridge, Middlesex UB11 1BT.

POM S1A

Date of approval: February 2019 Zinc code: UK/DTGRPV/0030/18(3)

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.