Juluca▼ (dolutegravir/rilpivirine) Prescribing Information

Please refer to Prescribing Information as follows:

- **England, Scotland & Wales (GB)**
- **Northern Ireland (NI) – see page 2**

Prescribing Information – England, Scotland & Wales (GB)

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 carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampicin, rifapentine, proton pump inhibitors, systemic dexamethasone (excluding single dose), St John's Wort or fampridine. **Special warnings/precautions:** Risk of hypersensitivity reactions. Discontinue Juluca immediately if suspected. Risks of prolongation of QTc interval, osteonecrosis, opportunistic infections, immune reactivation syndrome, increased weight, lipids and glucose. 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:** The safety and efficacy have not been studied in pregnancy. Not recommended during pregnancy due to observed lower exposure of dolutegravir and rilpivirine. Women of childbearing potential should be counselled about the potential risk of neural tube defects with dolutegravir (a component of Juluca), including consideration of effective contraceptive measures. If a woman plans pregnancy, the benefits and the risks of continuing treatment with Juluca should be discussed with the patient. Do not breast-feed. **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. **MA number:** PLGB 35728/0034. **MA holder:** ViiV Healthcare UK Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS, UK. Further information available from customercontactuk@gsk.com Freephone 0800 221 441.

POM

Date of approval: October 2021 PI-0396v5

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.

Prescribing Information – Northern Ireland

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 carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampicin, rifapentine, proton pump inhibitors, systemic dexamethasone (excluding single dose), St John's Wort or fampridine. **Special warnings/precautions:** Risk of hypersensitivity reactions. Discontinue Juluca immediately if suspected. Risks of prolongation of QTc interval, osteonecrosis, opportunistic infections, immune reactivation syndrome, increased weight, lipids and glucose. 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:** The safety and efficacy have not been studied in pregnancy. Not recommended during pregnancy due to observed lower exposure of dolutegravir and rilpivirine. Women of childbearing potential should be counselled about the potential risk of neural tube defects with dolutegravir (a component of Juluca), including consideration of effective contraceptive measures. If a woman plans pregnancy, the benefits and the risks of continuing treatment with Juluca should be discussed with the patient. Do not breast-feed. **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/ suicide attempt/ completed suicide (particularly in patients with a pre-existing history of depression or psychiatric illness), panic attack, acute hepatic failure. Changes in laboratory biochemistries: elevations of ALT, AST, pancreatic amylase, bilirubin and CPK. **Basic NHS costs:** £699.02 for 30 tablets. **MA number:** EU/1/18/1282/001. **MA holder:** ViiV Healthcare BV, Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Netherlands. Further information available from customercontactuk@gsk.com Freephone 0800 221 441.

POM

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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.

Date of approval of combined PI: March 2022 PI-8748v4