

Dovato dolutegravir 50mg/lamivudine 300mg tablets

Prescribing Information - GB

See Summary of Product Characteristics (SmPC) before prescribing

Adverse events should be reported. For the UK, reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/> or search for **MHRA Yellowcard** in the **Google Play** or **Apple App store**. Adverse events should also be reported to GSK via the [GSK Reporting Tool](#) or on 0800 221441.

Indication: HIV-1 in adults & adolescents above 12 years of age weighing ≥ 40 kg, with no known or suspected resistance to the integrase inhibitor class, or lamivudine.

Dosing: One tablet once daily with or without food. Use an additional 50mg tablet of dolutegravir approximately 12 hours after the dose of Dovato when co-administered with efavirenz, nevirapine, tipranavir/ritonavir, etravirine (without boosted PI), carbamazepine, oxcarbazepine, phenytoin, phenobarbital, St John's Wort or rifampicin.

Elderly: Limited data in 65+ yrs. Not recommended in patients with creatinine clearance < 30 mL/min. Caution in severe hepatic impairment.

Contraindications: Hypersensitivity to any ingredient. Co-administration with substrates of OCT-2 with narrow therapeutic windows, such as fampridine. **Special warnings/precautions:** Risk of hypersensitivity reactions. Discontinue dolutegravir and other suspect agents immediately. Risks of osteonecrosis, immune reactivation syndrome, increased weight, lipids and glucose. Monitor LFTs in Hepatitis B/C co-infection and ensure effective Hepatitis B therapy. Patients with sustained creatinine clearance between 30 and 49 mL/min who receive Dovato should be monitored for lamivudine-related adverse events, notably haematologic toxicities, associated with higher lamivudine exposure. If necessary, consider use of separate components to adjust dosage. Caution with metformin: monitor renal function and consider metformin dose adjustment. Use with etravirine requires boosted PI or increased dose of dolutegravir. Use with

Mg/Al-containing antacids requires dosage separation. Use with calcium, multivitamins or iron also requires dosage separation if not taken at the same time with food. Use with cladribine or emtricitabine not recommended. When possible, avoid chronic co-administration of sorbitol or other osmotic acting alcohols (see SmPC section 4.5). If unavoidable, consider more frequent viral load monitoring. **Pregnancy/ lactation:** See SmPC for details. Dovato can be used during pregnancy if clinically needed. Do not breast-feed. **Side effects:** See SmPC for full details. Headache, GI disturbance, insomnia, abnormal dreams, depression, anxiety, dizziness, somnolence, rash, pruritus, alopecia, fatigue, arthralgia, myalgia, weight increased, hypersensitivity, suicidal ideation/suicide attempt/completed suicide (particularly in patients with a history of depression or psychiatric illness), panic attack, hepatitis, neutropenia, anaemia, thrombocytopenia, pure red cell aplasia, sideroblastic anaemia, acute hepatic failure, increased bilirubin, pancreatitis, angioedema, rhabdomyolysis, lactic acidosis, peripheral neuropathy. Elevations of ALT, AST and CPK. **Basic NHS costs:** £656.26 for 30 tablets (bottles and blister packs). **MA number:** PLGB 35728/0052. **MA holder:** ViiV Healthcare UK Limited, 79 New Oxford Street, London WC1A 1DG, UK. Further information available from: customercontactuk@gsk.com Freephone 0800 221 441.

POM

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