

Dovato (dolutegravir/lamivudine) 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)

Dovato dolutegravir 50mg/lamivudine 300mg tablets

See Summary of Product Characteristics (SmPC) before prescribing

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:** The safety and efficacy have not been studied in pregnancy. Women of childbearing potential should be counselled about the potential risk of neural tube defects with dolutegravir (a component of Dovato), including consideration of effective contraceptive measures. If a woman plans pregnancy, the benefits and the risks of continuing treatment with Dovato should be discussed with the patient. If a pregnancy is confirmed in the first trimester while on Dovato, the benefits and risks of continuing Dovato versus switching to another antiretroviral regimen should be discussed with the patient taking the gestational age and the critical time period of neural tube defect development into account. Most neural tube defects occur within the first 4 weeks of embryonic development after conception (approximately 6 weeks after the last menstrual period). Dovato may be used during the second and third trimester of pregnancy when the expected benefit justifies the potential risk to the foetus. 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, blood dyscrasias, 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, 980 Great West Road, Brentford, Middlesex, TW8 9GS, UK. Further information available from: customercontactuk@gsk.com Freephone 0800 221 441.

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Date of approval: February 2024

PI-2451v8

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

Dovato dolutegravir 50mg/lamivudine 300mg tablets

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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:** The safety and efficacy have not been studied in pregnancy. Women of childbearing potential should be counselled about the potential risk of neural tube defects with dolutegravir (a component of Dovato), including consideration of effective contraceptive measures. If a woman plans pregnancy, the benefits and the risks of continuing treatment with Dovato should be discussed with the patient. If a pregnancy is confirmed in the first trimester while on Dovato, the benefits and risks of continuing Dovato versus switching to another antiretroviral regimen should be discussed with the patient taking the gestational age and the critical time period of neural tube defect development into account. Most neural tube defects occur within the first 4 weeks of embryonic development after conception (approximately 6 weeks after the last menstrual period). Dovato may be used during the second and third trimester of pregnancy when the expected benefit justifies the potential risk to the foetus. 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 pre-existing history of depression or psychiatric illness), panic attack, hepatitis, blood dyscrasias, 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:** EU/1/19/1370/001. **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.

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Date of approval: February 2024

PI-8186v6

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: February 2024

PI-8219v9