Dovato
dolutegravir/lamivudine

POWERFUL, DURABLE, NON-INFERIOR EFFICACY vs a 3-drug regimen[1,2]

HIGH BARRIER TO RESISTANCE[1,2]

TDF, TAF AND ABC FREE[3]

REAL-WORLD STUDIES SUPPORT FINDINGS FROM PHASE III TANGO STUDY[2,4-15*†]

LOW RISK OF VIROLOGICAL FAILURE

HIGH BARRIER TO RESISTANCE

LOW RATE OF TREATMENT DISCONTINUATIONS

>2,000 SUPPRESSED-SWITCH PATIENTS

12 STUDIES

5 COUNTRIES

DIVERSE PATIENT POPULATIONS

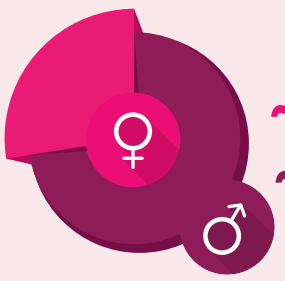
AGE RANGE
YEARS[4-15]

19 YEARS ➤ 87 YEARS

PRIMARY REASONS FOR SWITCHING[4,5,9,10,12]

- TOXICITY (INCLUDING RENAL, BONE, CV AND GI)
- TOLERABILITY
- DDIs
- CONVENIENCE
- SIMPLIFICATION/OPTIMISATION

GENDER[4-15]



~30% FEMALE
~70% MALE

CD4+ T-CELL COUNT AT BASELINE
LOWEST/HIGHEST (cells/mm^3)[4-6,8,10-15]

67 947

NUMBER OF PREVIOUS TREATMENT LINES
RANGE, MEDIAN=6.5[9-12,14,15]

1 TO 12

DURATION OF ART
YEARS, MEDIAN=10.5[4,8,10-12,14,15]

508 PATIENTS WITH HCV CO-INFECTION[4,8,10,12,13,15]

*All data reported as available. From a literature search up to April 2020, for studies including adult patients with no known or suspected resistance to integrase inhibitors or lamivudine.
†Note: For some studies, baseline characteristics are reported for the total population.

DOVATO is indicated for the treatment of HIV-1 in adults and adolescents above 12 years weighing at least 40 kg, with no known or suspected resistance to the integrase inhibitor class, or lamivudine.

Dovato
dolutegravir/lamivudine

Prescribing Information

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 >40kg, 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 < 50 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. Monitor LFTs in Hepatitis B/C co-infection and ensure effective Hepatitis B therapy. 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, hypersensitivity, suicidal ideation or suicide attempt, hepatitis, blood dyscrasias, acute hepatic failure, pancreatitis, angioedema, rhabdomyolysis, lactic acidosis, peripheral neuropathy. Elevations of ALT, AST and CPK.**Basic NHS costs:** £656.26 for 30 tablets. **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.

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.

References: 1. Cahn P et al. *J Acquir Immune Defic Syndr*. 2020;83(3):310-318. **2.** van Wyk J et al. *Clin Infect Dis*. 2020. doi:10.1093/cid/ciz1243. **3.** DOVATO Summary of Product Characteristics. April 2020. **4.** Borghetti A et al. *Clin Infect Dis*. 2020;ciaa313. doi:10.1093/cid/ciaa313. **5.** Castelli A et al. Presented at: 17th European AIDS Conference; November 6-9, 2019; Basel, Switzerland. Poster PE2/35. **6.** Diaco ND et al. *EClinicalMedicine*. 2018;6:21-25. **7.** Digaetano M et al. Presented at: HIV Drug Therapy Glasgow; October 28-31, 2018; Glasgow, UK. Poster P203. **8.** Gagliardini R et al. Presented at: Conference on Retroviruses and Opportunistic Infections; March 8-11, 2020; Boston, MA. Poster 0486. **9.** Hart J et al. Presented at: 25th Annual Conference of the British HIV Association; April 2-5, 2019; Bournemouth, UK. **10.** Hidalgo-Tenorio C et al. *Medicine*. 2019;98(32):e16813. **11.** Lanzafame M et al. *New Microbiol*. 2018;41(4):262-267. **12.** Maggiolo F et al. Presented at: HIV Drug Therapy Glasgow; October 28-31, 2018; Glasgow, UK. Poster P104. **13.** Moreno Zamora A et al. Presented at: 16th European AIDS Conference; October 25-27, 2017; Milan, Italy. Poster PE9/38. **14.** Pereira Goulart S et al. Presented at: 17th European AIDS Conference; November 6-9, 2019; Basel, Switzerland. Poster PE2/34. **15.** Teira R et al. Presented at 17th European AIDS Conference; November 6-9, 2019; Basel, Switzerland. Slides PS8/5.

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Product: DOVATO

Type: Promotional Material

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