

## Prescribing Information

### Tivicay dolutegravir 10mg, 25mg and 50mg tablets

See Summary of Product Characteristics before prescribing

**Indication:** HIV in >6 years and  $\geq 15$ kg as part of combination therapy. **Dosing:** *Adults & adolescents  $\geq 40$ kg:* 50mg once daily with or without food if no proven/ suspected integrase resistance. Children 6 to <12 years: dose according to bodyweight: 15-<20kg: 20mg once daily (2x10mg); 20-<30kg: 25mg once daily; 30-<40kg: 35mg once daily (1 x 25mg + 1 x 10mg); When co-administered with efavirenz, nevirapine, tipranavir/ritonavir, etravirine (without boosted PI), carbamazepine, oxcarbazepine, phenytoin, phenobarbital, St John's Wort or rifampicin, Tivicay 50mg twice daily in adults/adolescents or the weight-based once daily dose twice daily in paediatric patients. *Adults with proven or suspected integrase resistance:* 50mg twice daily preferably with food. Limited data in paediatric patients with proven/suspected integrase resistance. *Elderly:* Limited data in 65+ yrs. 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 if suspected. The two-drug regimen of dolutegravir and lamivudine is only suitable for the treatment of HIV-1 infection where there is no known or suspected resistance to the integrase inhibitor class, or to

lamivudine. 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, calcium, multivitamins or iron requires dosage separation. **Pregnancy/ lactation:** Before initiating dolutegravir, women of childbearing potential (WOCBP) should undergo pregnancy testing. WOCBP who are taking dolutegravir should use effective contraception. Dolutegravir should not be used during the first trimester due to the potential risk of neural tube defects, unless there is no alternative. Dolutegravir should only 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, rash, pruritus, fatigue, elevations of ALT, AST and CPK, arthralgia, myalgia, hypersensitivity, suicidal ideation or suicide attempt, acute hepatic failure. **Basic NHS costs:** £498.75 for 30 x 50mg tablets; £99.75 for 30 x 10mg tablets; £249.38 for 30 x 25mg tablets. **MA numbers:** 50mg: EU/1/13/892/001; 10mg: EU/1/13/892/003; 25mg: EU/1/13/892/005. **MA holder:** ViiV Healthcare BV, Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Netherlands. Further information available from [customercontactuk@gsk.com](mailto:customercontactuk@gsk.com) Freephone 0800 221 441.

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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](http://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.