

## Prescribing Information

### Tivicay<sup>▼</sup> 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/ 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 dofetilide.

**Warnings/precautions:** Risk of hypersensitivity reactions. Discontinue

dolutegravir and other suspect agents immediately if suspected. 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:** Not recommended. Avoid breast-feeding. **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 (EU/1/13/892/001). £99.75 for 30 x 10mg tablets (EU/1/13/892/003). £249.38 for 30 x 25mg tablets (EU/1/13/892/005). MA holder: ViiV Healthcare BV, Huis ter Heideweg 62, 3705 LZ Zeist, Netherlands. Further information available from Customer Contact Centre, GlaxoSmithKline UK Ltd, Stockley Park West, Uxbridge, Middlesex UB11 1BT.

**POM** S1A

Trade marks are owned by or licensed to the ViiV Healthcare group of companies.

Date of approval: July 2018

Zinc code: UK/DLG/0055/13(14)

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.

Adverse events should be reported. For Ireland, adverse events should be reported directly to the HPRA; Freepost, Pharmacovigilance Section, Health Products Regulatory Authority, Earlsfort Terrace, Dublin 2, Tel: +353 1 676 4971, [medsafety@hpra.ie](mailto:medsafety@hpra.ie). Adverse events should also be reported to GlaxoSmithKline on 1800 244 255.