

Tivicay (dolutegravir) 5mg Dispersible Tablets Prescribing Information

Please refer to Prescribing Information as follows:

- England, Scotland & Wales (GB)
- Northern Ireland (NI) – see page 3

Prescribing Information – England, Scotland & Wales (GB)

Tivicay (dolutegravir) 5mg Dispersible Tablets

See Summary of Product Characteristics before prescribing

Indication: HIV in adults, adolescents and children ≥ 4 weeks of age and weighing ≥ 3 kg, as part of combination therapy. **Dosing:** Dispersible tablets may be dispersed in water (see package leaflet for instructions) or swallowed whole (one at a time) with water, with or without food. *Adults with no proven/suspected integrase resistance:* 30 mg (six 5 mg dispersible tablets) orally once daily. *Adults with proven/suspected integrase resistance:* 30 mg (six 5 mg dispersible tablets) twice daily preferably with food. Adolescents, children and infants aged ≥ 4 weeks and weighing ≥ 3 kg: *Patients infected with HIV-1 without resistance to the integrase class:* dose according to bodyweight and age: 3 kg- <6 kg: 5mg once daily; 6 kg- <10 kg (aged <6 months): 10mg once daily; 6 kg- <10 kg (aged ≥ 6 months): 15mg once daily; 10 kg- <14 kg; 20mg once daily; 14 kg- <20 kg; 25mg once daily; ≥ 20 kg: 30mg once daily. For children over 6 kg, the dose may be split and given twice daily – see SmPC for details. Tivicay is available as film-coated tablets for patients aged 6 years and above and weighing ≥ 14 kg. For patients changing between dispersible tablets and film-coated tablets, refer to separate SmPCs for dosing as dispersible tablets are not bioequivalent to film-coated tablets. When co-administered with efavirenz, nevirapine, tipranavir/ritonavir, etravirine (without boosted PI), carbamazepine, oxcarbazepine, phenytoin, phenobarbital, St John's Wort or rifampicin in the absence of integrase resistance, the recommended once daily dose should be given twice daily; in the presence of integrase class resistance, alternative combinations should be considered. *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, increased weight, lipids, glucose. 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:** Women of childbearing potential should be counselled about the potential risk of neural tube defects with dolutegravir, including consideration of effective contraceptive measures. If a woman plans pregnancy, the benefits and risks of continuing treatment with dolutegravir should be discussed with the patient. If a pregnancy is confirmed in the first trimester while on dolutegravir, the benefits and risks of continuing dolutegravir 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). Dolutegravir 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, rash, pruritus, fatigue, weight increased, elevations of ALT, AST and CPK, arthralgia, myalgia, hypersensitivity, suicidal ideation/suicide attempt/completed suicide

(particularly in patients with a history of depression or psychiatric illness), panic attack, acute hepatic failure, increased bilirubin. **Basic NHS costs:** £159.60 for 60 x 5 mg tablets. **MA number:** PLGB 35728/0059. **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.

POM

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

Date of approval: June 2023

PI-7443v3

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 (NI)

Tivicay (dolutegravir) 5mg Dispersible Tablets

See Summary of Product Characteristics before prescribing

Indication: HIV in adults, adolescents and children ≥ 4 weeks of age and weighing ≥ 3 kg, as part of combination therapy. **Dosing:** Dispersible tablets may be dispersed in water (see package leaflet for instructions) or swallowed whole (one at a time) with water, with or without food. *Adults with no proven/suspected integrase resistance:* 30 mg (six 5 mg dispersible tablets) orally once daily. *Adults with proven/suspected integrase resistance:* 30 mg (six 5 mg dispersible tablets) twice daily preferably with food. Adolescents, children and infants aged ≥ 4 weeks and weighing ≥ 3 kg: *Patients infected with HIV-1 without resistance to the integrase class:* dose according to bodyweight and age: 3 kg- <6 kg: 5mg once daily; 6 kg- <10 kg (aged <6 months): 10mg once daily; 6 kg- <10 kg (aged ≥ 6 months): 15mg once daily; 10 kg- <14 kg: 20mg once daily; 14 kg- <20 kg: 25mg once daily; ≥ 20 kg: 30mg once daily. For children over 6 kg, the dose may be split and given twice daily – see SmPC for details. Tivicay is available as film-coated tablets for patients aged 6 years and above and weighing ≥ 14 kg. For patients changing between dispersible tablets and film-coated tablets, refer to separate SmPCs for dosing as dispersible tablets are not bioequivalent to film-coated tablets. When co-administered with efavirenz, nevirapine, tipranavir/ritonavir, etravirine (without boosted PI), carbamazepine, oxcarbazepine, phenytoin, phenobarbital, St John's Wort or rifampicin in the absence of integrase resistance, the recommended once daily dose should be given twice daily; in the presence of integrase class resistance, alternative combinations should be considered. *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, increased weight, lipids, glucose. 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:** Women of childbearing potential should be counselled about the potential risk of neural tube defects with dolutegravir, including consideration of effective contraceptive measures. If a woman plans pregnancy, the benefits and risks of continuing treatment with dolutegravir should be discussed with the patient. If a pregnancy is confirmed in the first trimester while on dolutegravir, the benefits and risks of continuing dolutegravir 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). Dolutegravir 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, rash, pruritus, fatigue, weight increased, elevations of ALT, AST and CPK, arthralgia, myalgia, hypersensitivity, suicidal ideation/ suicide attempt/ completed suicide (particularly in patients with a pre-existing history of depression or psychiatric illness), panic attack, acute hepatic failure, increased bilirubin. **Basic NHS costs:** £159.60 for 60 x 5 mg tablets. **MA number:** EU/1/13/892/007. **MA holder:** ViiV Healthcare BV, Van Asch van Wijkstraat 55H, 3811 LP Amersfoort, Netherlands. Further information available from customercontactuk@gsk.com Freephone 0800 221 441.

POM

Date of approval: September 2022

PI-9166v3

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: June 2023

PI-9171v4