

Tivicay (dolutegravir) 10mg, 25mg and 50mg Film Coated 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) 10mg, 25mg and 50mg film-coated tablets

See Summary of Product Characteristics before prescribing

Indication: HIV in adults, adolescents and children ≥ 6 years of age and weighing ≥ 14 kg as part of combination therapy. **Dosing:** *Adults with no proven/suspected integrase resistance:* 50mg once daily with or without food. *Adults with proven/suspected integrase resistance:* 50mg twice daily preferably with food. *Adolescents aged 12 to 18 years, and weighing ≥ 20 kg with no proven/suspected integrase resistance:* 50mg once daily with or without food or if preferred, 25mg twice daily. Not recommended in presence of integrase resistance. *Children 6 to <12 years with no proven/suspected integrase resistance:* dose according to bodyweight: 14- <20 kg: 40mg once daily or 20mg twice daily; ≥ 20 kg: 50mg once daily or 25mg twice daily. Not recommended in presence of integrase resistance. Use Tivicay dispersible tablets for patients aged 4 weeks and above and weighing ≥ 3 kg, or for patients in whom film-coated tablets are not appropriate. Refer to separate SmPC 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, Tivicay 50mg twice daily or the weight-based once daily dose twice daily in paediatric patients; 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:** £498.75 for 30 x 50mg tablets;

£99.75 for 30 x 10mg tablets; £249.38 for 30 x 25mg tablets. **MA numbers:** 50mg: PLGB 35728/0046; 10mg: PLGB 35728/0044; 25mg: PLGB 35728/0045 . **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

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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.

Prescribing Information – Northern Ireland

Tivicay (dolutegravir) 10mg, 25mg and 50mg film-coated tablets

See Summary of Product Characteristics before prescribing

Indication: HIV in adults, adolescents and children ≥ 6 years of age and weighing ≥ 14 kg as part of combination therapy. **Dosing:** *Adults with no proven/suspected integrase resistance:* 50mg once daily with or without food. *Adults with proven/suspected integrase resistance:* 50mg twice daily preferably with food. *Adolescents aged 12 to 18 years, and weighing ≥ 20 kg with no proven/ suspected integrase resistance:* 50mg once daily with or without food or if preferred, 25mg twice daily. Not recommended in presence of integrase resistance. *Children 6 to <12 years with no proven/suspected integrase resistance:* dose according to bodyweight: 14-<20kg: 40mg once daily or 20mg twice daily; ≥ 20 kg: 50mg once daily or 25mg twice daily. Not recommended in presence of integrase resistance. Use Tivicay dispersible tablets for patients aged 4 weeks and above and weighing ≥ 3 kg, or for patients in whom film-coated tablets are not appropriate. Refer to separate SmPC 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, Tivicay 50mg twice daily or the weight-based once daily dose twice daily in paediatric patients; 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:** £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 Wijkstraat 55H, 3811 LP Amersfoort, Netherlands. Further information available from customercontactuk@gsk.com Freephone 0800 221 441.

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