

Prescribing Information – GB (England, Scotland & Wales)

Triumeq dolutegravir 5mg/abacavir 60mg/lamivudine 30mg dispersible tablets

See Summary of Product Characteristics (SmPC) before prescribing.

Indication: HIV in children weighing ≥ 14 kg to < 25 kg. Screen for HLA-B*5701 prior to use. Do not use if HLA-B*5701 positive. **Dosing:** Tablet(s) should be fully dispersed in 20 mL of drinking water before swallowing, with or without food. See package leaflet for instructions. Do not chew, cut or crush the tablets. Dose according to body weight. ≥ 14 kg to < 20 kg: 5 tablets once daily; 20 - < 25 kg: 6 tablets once daily. Use an additional dose of dolutegravir dispersible tablets approximately 12 hours after the dose of Triumeq when co-administered with rifampicin, carbamazepine, oxcarbazepine, phenytoin, phenobarbital, St. John's Wort, etravirine (without boosted protease inhibitors), efavirenz, nevirapine, or tipranavir/ritonavir as follows. ≥ 14 kg to < 20 kg: an extra 25mg; 20 - < 25 kg: an extra 30mg. *Elderly:* Limited data in 65+ yrs. *Creatinine clearance < 50 mL/min or moderate/severe hepatic impairment:* Not recommended. Monitor closely in mild hepatic impairment, including monitoring of abacavir plasma levels if feasible. **Contraindications:** Hypersensitivity to any ingredient. Co-administration with substrates of OCT-2 with narrow therapeutic windows, such as fampridine. **Special warnings/precautions:** Both abacavir and dolutegravir are associated with risk of hypersensitivity reactions (HSR). Do not initiate in HLA-B*5701+ or previous suspected abacavir HSR. Stop Triumeq without delay if HSR suspected. Never reintroduce any dolutegravir- or abacavir-containing product after suspected HSR. Not recommended in presence of integrase inhibitor resistance; insufficient data to recommend a dose in adolescents, children or infants with integrase inhibitor resistance. Risks of immune reactivation syndrome, osteonecrosis, increased weight, lipids, glucose. Monitor LFTs in Hepatitis B/C co-infection. Inconsistent data from clinical and observational studies suggest an increased risk of cardiovascular events in patients treated with abacavir. Minimise all modifiable CV risk factors. Consider alternative options for patients with high CV risk. Use with cladribine not recommended. Use with Mg/Al-containing antacids requires dosage separation. Use with supplements or

multivitamins containing calcium, iron or magnesium also requires dosage separation if not taken at the same time with food. Caution with metformin: monitor renal function and consider metformin dose adjustment. Abacavir increased riociguat concentrations. Consider dose adjustment of riociguat. 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: Women of childbearing potential should be counselled about the potential risk of neural tube defects with dolutegravir (a component of Triumeq), including consideration of effective contraceptive measures. If a woman plans pregnancy, the benefits and the risks of continuing treatment with Triumeq should be discussed with the patient. If a pregnancy is confirmed in the first trimester while on Triumeq, the benefits and risks of continuing Triumeq 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). Triumeq 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 details. Headache, insomnia, sleep/dream disorders, GI disturbance, fatigue, hypersensitivity, anorexia, depression, anxiety, dizziness, somnolence, lethargy, malaise, cough, nasal symptoms, rash, pruritus, alopecia, arthralgia, myalgia, weight increased, asthenia, fever, elevations of ALT, AST and CPK, blood dyscrasias, suicidal ideation/suicide attempt/completed suicide (particularly in patients with a history of depression or psychiatric illness), panic attack, rhabdomyolysis, acute hepatic failure, increased bilirubin, lactic acidosis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis. **Basic NHS costs:** 90 tablets: £238.50. **MA number:** PLGB 35728/0060. **MA holder:** ViiV Healthcare UK Ltd, 980 Great West Road, Brentford, Middlesex TW8 9GS. Further information is available from 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 <https://yellowcard.mhra.gov.uk/> or search for **MHRA Yellowcard** in the **Google Play or Apple App store**. Adverse events should also be reported to GlaxoSmithKline on 0800 221441.