## Triumeq dolutegravir 50mg/abacavir 600mg/lamivudine 300mg tablets Prescribing Information – GB

See Summary of Product Characteristics (SmPC) before prescribing.

Adverse events should be reported. For the UK, reporting forms and information can be found at <a href="https://yellowcard.mhra.gov.uk/">https://yellowcard.mhra.gov.uk/</a> or search for MHRA Yellowcard in the Google Play or Apple App store. Adverse events should also be reported to GSK via the <a href="https://gsk.google.

Indication: HIV in adults, adolescents and children weighing ≥ 25kg. Screen for HLA-B\*5701 prior to use. Do not use if HLA-B\*5701 positive. Dose: one tablet once daily with or without food. Use an additional 50mg tablet of dolutegravir approximately 12 hours after the dose of Triumeg when co-administered with rifampicin, carbamazepine, oxcarbazepine, phenytoin, phenobarbital, St. John's Wort, etravirine (without boosted protease inhibitors), efavirenz, nevirapine, or tipranavir/ritonavir. Elderly: Limited data in 65+ yrs. Creatinine clearance <30mL/min or moderate/severe hepatic impairment: Not recommended. Monitor closely in mild hepatic impairment. 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 Triumeg without delay if HSR suspected. Never reintroduce any dolutegravir- or abacavir-containing product after suspected HSR. Not recommended in presence of integrase inhibitor resistance, as the recommended dolutegravir dose in adults is 50mg twice daily; insufficient data to recommend a dose in adolescents or children with integrase inhibitor resistance. Risks of immune reactivation syndrome, osteonecrosis, increased weight, lipids, glucose. Monitor LFTs in Hepatitis B/C co-infection. Patients with sustained creatinine clearance between 30 and 49 mL/min who receive Triumeg should be monitored for lamivudine-related adverse events, notably haematologic toxicities, associated with higher lamivudine exposure. If necessary, consider use of separate components to adjust dosage. 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 coadministration of sorbitol or other osmotic acting alcohols (see SmPC section 4.5). If unavoidable, consider more frequent viral load monitoring. Pregnancy/lactation: See SmPC for details. Triumeq can be used during pregnancy if clinically needed. Do not breastfeed. 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, suicidal ideation/suicide attempt/completed suicide (particularly in patients with a history of depression or psychiatric illness), panic attack, neutropenia, anaemia, thrombocytopenia, pure red cell aplasia, sideroblastic anaemia, rhabdomyolysis, acute hepatic failure, increased bilirubin, lactic acidosis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis. Basic NHS costs: 30 tablets: £798.16. MA number: PLGB 35728/0035. MA holder: ViiV Healthcare UK Ltd. 79 New Oxford Street, London WC1A 1DG, UK. Further information is available from customercontactuk@gsk.com Freephone 0800 221 441.

POM

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