Triumeq (dolutegravir/abacavir/lamivudine) 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)
Triumeq dolutegravir 50mg/abacavir 600mg/lamivudine 300mg tablets
See Summary of Product Characteristics (SmPC) before prescribing.

Indication: HIV in over 12 years and $\geq$ *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 Triumeq 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 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, 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 Triumeq 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 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:** 30 tablets: £798.16. **MA number:** PLGB 35728/0035. **MA holder:** ViiV Healthcare UK Ltd, 980 Great West Road, Brentford, Middlesex TW8 9GS, UK. Further information is 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 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.

Prescribing Information – Northern Ireland
Triumeq dolutegravir 50mg/abacavir 600mg/lamivudine 300mg tablets
See Summary of Product Characteristics (SmPC) before prescribing.

Indication: HIV in over 12 years and ≥ *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 Triumeq 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 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, 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 Triumeq 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 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 pre-existing 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:** 30 tablets: £798.16. **MA number:** EU/1/14/940/001. **MA holder:** ViiV Healthcare BV, Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Netherlands. Further information is 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 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.

Date of approval of combined PI: January 2024 PI-8446v12