Kivexa abacavir 600mg/lamivudine 300mg tablets

Prescribing Information

See Summary of Product Characteristics (SmPC) before prescribing

Indications: HIV in adults, adolescents and children weighing at least 25 kg as part of combination therapy. Screen for HLA-B*5701 prior to use. **Dose:** one tablet daily with or without food. *Elderly:* No pharmacokinetic data in 65+ yrs. *Renal impairment*: Creatinine clearance <50ml/min: not recommended. *Hepatic impairment*: not recommended in moderate or severe hepatic impairment. Monitor closely in mild hepatic impairment. **Contraindications:** Hypersensitivity to any ingredient.

Warnings/precautions: Risk of hypersensitivity reactions (HSR). Do not initiate in patients who are HLA-B*5701 positive on screening or had previous suspected abacavir HSR. Stop Kivexa without delay if HSR suspected. Never re-introduce any abacavir-containing product after suspected HSR. Risks of virological failure, immune reactivation syndrome, osteonecrosis, increased weight, lipids, glucose. Monitor LFTs in Hepatitis B/C co-infection. Inconclusive data on relationship between abacavir and MI; minimise modifiable CV risk factors (e.g. smoking, hypertension, hyperlipidaemia). Use with cladribine, emtricitabine or high doses of co-trimoxazole not recommended. 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:** Not recommended. Avoid breast-feeding. **Side effects:** See SmPC for full details. Hypersensitivity, GI disturbance**,** headache, anorexia, insomnia, rash, fever, lethargy, fatigue, malaise, arthralgia, muscle disorders, nasal symptoms, cough, alopecia, blood dyscrasias, rhabdomyolysis, lactic acidosis, erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis. **Basic NHS costs:** 30 tablets: £352.25 EU/1/04/298/002. MA holder: ViiV Healthcare BV, Huis ter Heideweg 62, 3705 LZ Zeist, Netherlands. Further information is available from Customer Contact Centre, GlaxoSmithKline UK Ltd, Stockley Park West, Uxbridge, Middlesex UB11 1BT.

POM S1A

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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 GSK on 0800 221441.

Adverse events should be reported. For Ireland, adverse events should be reported directly to the HPRA; Freepost, Pharmacovigilance Section, Health Products Regulatory Authority, Earlsfort Terrace, Dublin 2, Tel: +353 1 676 4971, *medsafety@hpra.ie*. Adverse events should also be reported to GlaxoSmithKline on 1800 244 255.