

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. **Special 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.

POM

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PI-0393v2

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. Do not breast-feed. **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: £352.25 for 30 tablets. **MA number:** EU/1/04/298/002. **MA holder:** ViiV Healthcare BV, Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Netherlands. Further information available from: customercontactuk@gsk.com Freephone 0800 221 441.

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.