

Epivir - 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. **Dose:** Adults: one 300mg tablet daily with or without food. See SmPC for dosage in children and adolescents. Additional formulations available: 150mg tablets and Oral Solution (10mg/mL) – see SmPCs. *Elderly:* No specific data. *Renal impairment:* Creatinine clearance <50ml/min: see SmPC for dosage adjustment. *Hepatic impairment:* no dose adjustment required. **Contraindications:** Hypersensitivity to any ingredient.

Warnings/precautions: High risk of virological failure (when used in a triple nucleoside regimen), immune reactivation syndrome, osteonecrosis, increased weight, lipids, glucose. Monitor LFTs in Hepatitis B/C co-infection. 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. Headache, GI disturbance, insomnia, cough, nasal symptoms, rash, alopecia, arthralgia, muscle disorders, fatigue, malaise, fever, blood dyscrasias, pancreatitis, hepatitis, angioedema, rhabdomyolysis, lactic acidosis, peripheral neuropathy. Transient increases in liver enzymes.

Basic NHS costs: 30 tablets: £157.51
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.

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UK/3TC/0001/18(1)

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 HPR; 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.