

Product Update

emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg, rilpivirine (as hydrochloride) 25mg, film-coated tablet (Eviplera®) (No. 759/12)

Gilead Sciences Limited

13 January 2012

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHS Scotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg, rilpivirine (as hydrochloride) 25mg, film-coated tablet (Eviplera®) is accepted for use in NHS Scotland.

Indication under review: treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naive adult patients with a viral load \leq 100,000 HIV-1 RNA copies/ml.

As with other antiretroviral therapies, genotypic resistance testing should inform the use of Eviplera®. This combination tablet has been shown to be bioequivalent to the individual components given separately. It is available at pro rata cost to the individual components and may be used to simplify the regimen of patients for whom this combination of HIV therapies is appropriate at the doses provided in this fixed dose combination.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

This assessment is based on data submitted by the applicant company up to and including 14 November 2011.

Chairman, Scottish Medicines Consortium