

Abbreviated Submission

ledipasvir/sofosbuvir 90mg/400mg film-coated tablet (Harvoni®)

SMC No 1343/18

Gilead Sciences

4 May 2018

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

ledipasvir/sofosbuvir (Harvoni®) is accepted for restricted use within NHS Scotland.

Indication under review: treatment of chronic hepatitis C (CHC) in adolescents aged 12 to <18 years.

SMC restriction: genotype 1 and 4 CHC only.

SMC has previously accepted ledipasvir/sofosbuvir for use in adults with genotype 1 and 4 CHC.

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 02 March 2018.

Chairman
Scottish Medicines Consortium

Published 11 June 2018