

Product Update:

ursodeoxycholic acid 500mg film-coated tablets (Ursofalk®)
SMC No: (889/13)

Dr Falk Pharma UK Ltd

05 July 2013

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

ursodeoxycholic acid 500mg film-coated tablets (Ursofalk®) is accepted for use within NHS Scotland.

Indication under review: for the dissolution of cholesterol gallstones in the gall bladder. The gallstones must not show as shadows on X-ray images and should not exceed 15mm in diameter. The gall bladder must be functioning despite the gallstone(s).

For the treatment of primary biliary cirrhosis (PBC), provided there is no decompensated hepatic cirrhosis.

Ursodeoxycholic acid 500mg film-coated tablets have demonstrated bioequivalence to ursodeoxycholic acid capsules at the same dose. Relative costs may vary slightly depending on the pack size used.

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 15 May 2013.

**Chairman,
Scottish Medicines Consortium**

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