



Final Appraisal Recommendation

Advice No: 1016 – April 2016

**Ursodeoxycholic acid (Ursofalk®) 250 mg hard capsules,
250 mg/5 ml suspension, 500 mg film-coated tablets**

Limited submission by Dr Falk Pharma UK Ltd

Recommendation of AWMSG

Ursodeoxycholic acid (Ursofalk®) is recommended for use within NHS Wales for the treatment of hepatobiliary disorders associated with cystic fibrosis in children aged 1 month to 18 years.

Additional note(s):

- Please refer to the Summary of Product Characteristics for the full licensed indication.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 2610), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

This recommendation was ratified by Welsh Government and will be considered for review every three years.

Marketing authorisation holder on first issue	Dr Falk Pharma UK Ltd
Date of first issue	April 2016
Last reviewed	February 2019

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500 mg film-coated tablets. April 2016.



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