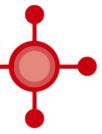
All Wales Medicines Strategy Group





Final Appraisal Recommendation Advice No: 0815 – March 2015

Bedaquiline (Sirturo®▼) 100 mg tablets

Submission by Janssen-Cilag Ltd

Recommendation of AWMSG

Bedaquiline (Sirturo[®]) is recommended as an option for use within NHS Wales for use as part of an appropriate combination regimen for pulmonary multidrug-resistant tuberculosis in adult patients when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability.

Additional note(s):

AWMSG considered that bedaquiline (Sirturo[®]

▼) satisfies the AWMSG criteria for ultra-orphan drug status.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 1334), 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 has been ratified by Welsh Government and will be considered for review every three years.

Marketing authorisation holder on first issue	Janssen Cilag Ltd
Date of first issue	March 2015
Last reviewed	March 2018

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All Wales Medicines Strategy Group. Final Appraisal Recommendation − 0815: Bedaquiline (Sirturo®▼) 100 mg tablets. March 2015.



NICE has accredited the process used by the All Wales Medicines Strategy Group (AWMSG) to produce its final appraisal recommendation. Accreditation is valid for 5 years from October 2011. More information on accreditation can be viewed at www.evidence.nhs.uk.