

Product Update:

midodrine hydrochloride (Bramox[®]) 2.5mg, 5mg tablets

SMC No. (1094/15)

Brancaaster Pharma Ltd

4 September 2015

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 Scotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

midodrine hydrochloride (Bramox[®]) is accepted for use within NHS Scotland.

Indication under review: in adults for the treatment of severe orthostatic hypotension due to autonomic dysfunction when corrective factors have been ruled out and other forms of treatment are inadequate.

Midodrine hydrochloride (Bramox[®]) 5mg tablets have been shown to be bioequivalent to the unlicensed midodrine 5mg product currently in use in NHS Scotland. The availability of midodrine hydrochloride (Bramox[®]) will allow the prescribing of a licensed medicinal product, with a resultant small net budget impact, based on estimates from primary and secondary prescribing and expenditure data from 2013/14.

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 31 July 2015,

**Chairman,
Scottish Medicines Consortium**