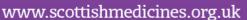
Scottish Medicines Consortium

Providing advice about the status of all newly licensed medicines



Delta House 50 West Nile Street Glasgow G1 2NP Tel 0141 225 6999 Chairman: Professor Jonathan G Fox

Product Update:

canagliflozin plus metformin 50mg/850mg and 50mg/1000mg immediaterelease tablets (Vokanamet[®]) SMC No. (1019/14) Janssen-Cilag Ltd

05 December 2014

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

canagliflozin plus metformin (Vokanamet[®]) is accepted for restricted use within NHS Scotland.

Indication under review: in adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control:

- in patients not adequately controlled on their maximally tolerated doses of metformin alone;
- in patients on their maximally tolerated doses of metformin along with other glucoselowering medicinal products, including insulin, when these do not provide adequate glycaemic control;
- in patients already being treated with the combination of canagliflozin and metformin as separate tablets.

SMC restriction: use in patients for whom a combination of canagliflozin and metformin is an appropriate choice of therapy

Canagliflozin in combination with metformin has been shown to be bioequivalent to canagliflozin and metformin administered separately and canagliflozin administered twice daily has been shown to provide similar exposure to the equivalent dose administered once daily.

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 16 October 2014.

Chairman, Scottish Medicines Consortium