

**sitagliptin 50 mg and metformin hydrochloride 1000 mg tablets
(Janumet® 50/1000) (No: 492/08)**

Merck Sharp and Dohme Ltd

Product Update

04 July 2008 (Issued 09 April 2010)

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

sitagliptin 50 mg and metformin hydrochloride 1000 mg (Janumet® 50/1000): is accepted for restricted use within NHS Scotland.

Licensed indication under review: as an adjunct to diet and exercise to improve glycaemic control in patients with type 2 diabetes mellitus inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of sitagliptin and metformin.

SMC restriction: restricted to use in patients for whom a combination of sitagliptin and metformin is an appropriate choice of therapy and only when the addition of sulphonylureas to metformin monotherapy is not appropriate. Sitagliptin represents an alternative to other agents such as thiazolidinediones.

Efficacy of sitagliptin when added to metformin, as assessed by measurement of HbA1c, is similar to sulphonylurea and thiazolidinedione drugs added at this stage in therapy. It appears to have minimal effects on body weight.

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 March 2010.

**Chairman,
Scottish Medicines Consortium**

Published 10 May 2010