

**sitagliptin 50mg plus metformin hydrochloride 1000mg
film-coated tablet (Janumet® 50/1000) (No: 627/10)**

MSD Ltd

Product Update

09 July 2010

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and Area Therapeutic Committees (ADTCs) on its use in NHS Scotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

sitagliptin plus metformin (Janumet® 50/1000): is accepted for use within NHS Scotland.

Licensed indication under review: In combination with a sulphonylurea (i.e., triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea.

For patients in whom triple combination therapy with metformin, a sulphonylurea and sitagliptin is appropriate it has the potential to reduce the pill burden at no additional cost.

When added to a sulphonylurea with metformin, sitagliptin has shown a modest effect on glycated haemoglobin (HbA_{1c}) levels. Note that a lower dose of the sulphonylurea may be required to reduce the risk of hypoglycaemia.

Sitagliptin/metformin is also licensed for use in triple combination therapy with a thiazolidinedione or as add-on to insulin. The manufacturer's submission related only to the use of sitagliptin/metformin in combination with a sulphonylurea, therefore SMC cannot recommend the use of sitagliptin/metformin in triple therapy with either a thiazolidinedione or insulin.

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 12 May 2010.

Chairman, Scottish Medicines Consortium

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