

Clinical Expert Summary Alogliptin/metformin (Vipdomet^{®▼}) 12.5 mg/1,000 mg film-coated tablets

Alogliptin/metformin (Vipdomet^{®▼}) is indicated for the treatment of adult patients aged 18 years and older with type 2 diabetes mellitus: as an adjunct to diet and exercise to improve glycaemic control in adult patients, inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of alogliptin and metformin; in combination with pioglitazone (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled on their maximal tolerated dose of metformin and pioglitazone; and in combination with insulin (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control¹.

1. Existing guidelines

The following guidelines were highlighted:

- National Institute for Health and Care Excellence (NICE). Clinical Guideline 87. Type 2 diabetes: the management of type 2 diabetes (2009)².

2. Disease prevalence/incidence

Experts highlight that in Wales, approximately 7%^{3,4} of the population are undergoing treatment for diabetes. Diabetes affects 16% of those over the age of 65 years. The incidence of diabetes is increasing rapidly, and as the prevalence of obesity rises, the prevalence of diabetes in adults is expected increase to 10.3% in 2020 and 11.5% by 2030^{3,5}. Current NICE guidance² recommends DPP-4 inhibitors as third-line therapy after treatment with metformin and sulphonylureas. Experts state that due to the favourable side effect profile, the DPP-4 class of medicines is being increasingly used, especially within the elderly population. Therefore, the number of potential patients who could be prescribed this medicine is significant.

3. Current treatment options

It was noted that at present, there are a number of DPP-4 inhibitors available in Wales (sitagliptin, saxagliptin, linagliptin and vildagliptin). Experts stated that sitagliptin was the first to market as has had the greatest share of prescribing. However, they note that linagliptin in particular, has been prescribed increasingly due to the lack of requirement for dose reductions in patients with chronic kidney disease. Experts highlighted that saxagliptin is currently the cheaper option in their Health Boards and as a result, is recommended for first-line treatment.

4. Unmet needs

No unmet needs were highlighted.

5. Knowledge of product in given indication

Experts highlighted that although alogliptin has a similar effect on HbA_{1c}, side effect profile, contraindications and combination licensing relative to other DPP-4 inhibitors, it does not have a monotherapy licence and there are no published randomised controlled trials of alogliptin added to metformin and a sulphonylurea⁶. However, they state there are two potential benefits that require consideration. Firstly, they estimate that alogliptin is 20% cheaper than both sitagliptin and linagliptin and is 16% cheaper than the current most cost-effective medicine, saxagliptin. Secondly, they suggest that alogliptin is the first DPP-4 inhibitor in its class to be launched with complete cardiovascular safety outcomes in patients considered to be high-risk. They note phase III studies with 5,380 patients who had experienced an acute coronary syndrome 15-90 days prior to randomisation did not demonstrate any increases in cardiovascular

death, non-fatal myocardial infarction or non-fatal stroke. These experts suggested that based on these factors it may well be considered as the first-line DPP-4 inhibitor. However, another expert felt they would not currently recommend alogliptin as first-line therapy on the basis of its cardiovascular data.

It should be noted that one expert involved in compiling this response declared a personal non-specific interest in relation to alogliptin/metformin for the indication under consideration.

REFERENCES

- 1 Takeda UK Ltd. Vipdomet[®]▼. Summary of Product Characteristics. May 2014. Available at: <http://www.medicines.org.uk/emc/medicine/28512/SPC/Vipdomet+12.5+mg+1000+mg+film+coated+tablets/>. Accessed Jun 2014.
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- 3 Welsh Government. Together for Health - A Diabetes Delivery Plan. A Delivery Plan up to 2016 for NHS Wales and its Partners. 2013. Available at: <http://www.diabetes.org.uk/Documents/Professionals/News,%20updates,%20prizes%20and%20alerts/Together%20for%20Health%20%E2%80%93%20A%20Diabetes%20Delivery%20Plan.pdf>. Accessed Aug 2014.
- 4 Welsh Government Knowledge and Analytical Services. National Statistics for Wales. Welsh Health Survey 2013: initial headline results. May 2014. Available at: <http://wales.gov.uk/docs/statistics/2014/140521-welsh-health-survey-2013-initial-headline-results-en.pdf>. Accessed Aug 2014.
- 5 Association of Public Health Observatories. Association of Public Health Observatories (APHO) Diabetes Prevalence Model for Wales. Sep 2010. Available at: <http://www.yhpho.org.uk/default.aspx?RID=81090>. Accessed Aug 2014.
- 6 National Institute for Health and Care Excellence. Evidence summary: new medicine (ESNM20). Type 2 diabetes: alogliptin. May 2013. Available at: <http://www.nice.org.uk/Advice/ESNM20>. Accessed Jul 2014.