19 May 2022
EMA/264071/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Sitagliptin/Metformin hydrochloride Accord

sitagliptin / metformin hydrochloride

On 19 May 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Sitagliptin/Metformin hydrochloride Accord, intended for the treatment of type 2 diabetes mellitus.

The applicant for this medicinal product is Accord Healthcare S.L.U.

Sitagliptin/Metformin hydrochloride Accord will be available as 50 mg/1000 mg and 50 mg/850 mg film-coated tablets. The active substances of Sitagliptin/Metformin hydrochloride Accord are sitagliptin and metformin hydrochloride, two oral blood glucose-lowering drugs used in combination in the treatment of diabetes (ATC code: A10BD07). Sitagliptin, a dipeptidyl peptidase 4 (DPP-4) inhibitor, improves glycaemic control in patients with type 2 diabetes by increasing the levels of active incretin hormones, leading to enhanced glucose-dependent insulin secretion and reduced glucagon release. Metformin hydrochloride, a member of the biguanide class, works mainly by inhibiting glucose production and reducing its absorption in the gut.

Sitagliptin/Metformin hydrochloride Accord is a generic of Janumet, which has been authorised in the EU since 16 July 2008. Studies have demonstrated the satisfactory quality of Sitagliptin/Metformin hydrochloride Accord, and its bioequivalence to the reference product Janumet. A question and answer document on generic medicines can be found here.

The full indication is:

> For adult patients with type 2 diabetes mellitus:
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> It is indicated as an adjunct to diet and exercise to improve glycaemic control in patients inadequately controlled on their maximal tolerated dose of metformin alone or those already being treated with the combination of sitagliptin and metformin.
>
> It is indicated 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

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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of metformin and a sulphonylurea.

It is indicated as triple combination therapy with a peroxisome proliferator-activated receptor gamma (PPARγ) agonist (i.e., a thiazolidinedione) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a PPARγ agonist.

It is also indicated as add-on to insulin (i.e., triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in patients when stable dose of insulin and metformin alone do not provide adequate glycaemic control.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.