27 January 2022
EMA/CHMP/687405/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vildagliptin/Metformin hydrochloride Accord

vildagliptin / metformin hydrochloride

On 27 January 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 Vildagliptin/Metformin hydrochloride Accord, intended for the treatment of type 2 diabetes mellitus.

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

Vildagliptin/Metformin hydrochloride Accord will be available as 50 mg/850 mg and 50 mg/1000 mg film-coated tablets. The active substances of Vildagliptin/Metformin hydrochloride Accord are vildagliptin and metformin hydrochloride, two oral blood glucose-lowering drugs used in combination in the treatment of diabetes (ATC code: A10BD08). Vildagliptin, 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.

Vildagliptin/Metformin hydrochloride Accord is a generic of Eucreas, which has been authorised in the EU since 14 November 2007. Studies have demonstrated the satisfactory quality of Vildagliptin/Metformin hydrochloride Accord, and its bioequivalence to the reference product Eucreas. A question and answer document on generic medicines can be found here.

The full indication is:

> Vildagliptin/Metformin hydrochloride Accord is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus:
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> - in patients who are inadequately controlled with metformin hydrochloride alone.
> - in patients who are already being treated with the combination of vildagliptin and metformin hydrochloride, as separate tablets.

[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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- in combination with other medicinal products for the treatment of diabetes, including insulin, when these do not provide adequate glycaemic control (see sections 4.4, 4.5 and 5.1 for available data on different combinations).

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.