



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 February 2022
EMA/CHMP/105005/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Sitagliptin Accord sitagliptin

On 24 February 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 Accord, intended for the treatment of type 2 diabetes mellitus.

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

Sitagliptin Accord will be available as 25 mg, 50 mg and 100 mg film-coated tablets. The active substance of Sitagliptin Accord is sitagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor (ATC code: A10BH01) which 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.

Sitagliptin Accord is a generic of Januvia, which has been authorised in the EU since 21 March 2007. Studies have demonstrated the satisfactory quality of Sitagliptin Accord and its bioequivalence to the reference product Januvia. A question and answer document on generic medicines can be found [here](#).

The full indication is:

For adult patients with type 2 diabetes mellitus, Sitagliptin Accord is indicated to improve glycaemic control:

as monotherapy:

- in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.

as dual oral therapy in combination with:

- metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control.

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



- a sulphonylurea when diet and exercise plus maximal tolerated dose of a sulphonylurea alone do not provide adequate glycaemic control and when metformin is inappropriate due to contraindications or intolerance.
- a peroxisome proliferator-activated receptor gamma (PPAR γ) agonist (i.e. a thiazolidinedione) when use of a PPAR γ agonist is appropriate and when diet and exercise plus the PPAR γ agonist alone do not provide adequate glycaemic control.

as triple oral therapy in combination with:

- a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.
- a PPAR γ agonist and metformin when use of a PPAR γ agonist is appropriate and when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.

Sitagliptin Accord is also indicated as add-on to insulin (with or without metformin) when diet and exercise plus stable dose of insulin 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.