14 October 2021
EMA/CHMP/570740/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Sitagliptin SUN

sitagliptin fumarate

On 14 October 2021, 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 SUN, intended for the treatment of type 2 diabetes mellitus.

The applicant for this medicinal product is Sun Pharmaceutical Industries Europe B.V.

Sitagliptin SUN will be available as 25 mg, 50 mg and 100 mg film-coated tablets. The active substance of Sitagliptin SUN is sitagliptin fumarate, 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 SUN is a generic of Januvia, which has been authorised in the EU since 21 March 2007. Studies have demonstrated Sitagliptin SUN to be of satisfactory quality and bioequivalent 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 SUN is indicated to improve glycaemic control:
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> as monotherapy:
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> - 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:
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> - 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

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- 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 (PPARγ) agonist (i.e. a thiazolidinedione) when use of a PPARγ agonist is appropriate and when diet and exercise plus the PPARγ 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 PPARγ agonist and metformin when use of a PPARγ agonist is appropriate and when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.

Sitagliptin SUN 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.