



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 May 2021
EMA/283685/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Xiliarx

vildagliptin

On 20 May 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Xiliarx. The marketing authorisation holder for this medicinal product is Novartis Europharm Limited.

The CHMP adopted a change to the existing indication as follows:²

Vildagliptin is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus:

- **as monotherapy in patients in whom metformin is inappropriate due to contraindications or intolerance.**
- **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).**

~~Vildagliptin is indicated in the treatment of type 2 diabetes mellitus in adults:~~

~~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, in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin,~~

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

² New text in bold, removed text as strikethrough



- ~~• a sulphonylurea, in patients with insufficient glycaemic control despite maximal tolerated dose of a sulphonylurea and for whom metformin is inappropriate due to contraindications or intolerance,~~
- ~~• a thiazolidinedione, in patients with insufficient glycaemic control and for whom the use of a thiazolidinedione is appropriate.~~

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.~~

~~Vildagliptin is also indicated for use in combination with insulin (with or without metformin) when diet and exercise plus a stable dose of insulin do not provide adequate glycaemic control.~~

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