20 May 2021
EMA/283696/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Zomarist

vildagliptin / metformin hydrochloride

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 Zomarist. The marketing authorisation holder for this medicinal product is Novartis Europharm Limited.

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

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

- **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.**
- **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).**

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

- ~~Zomarist is indicated in the treatment of adult patients who are unable to achieve sufficient glycaemic control at their maximally tolerated dose of oral metformin alone or who are already treated with the combination of vildagliptin and metformin as separate tablets.~~
- ~~Zomarist is indicated in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled with metformin and a sulphonylurea.~~

[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

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- ~~Zomarist is indicated in triple combination therapy with insulin as an adjunct to diet and exercise to improve glycaemic control in adult patients when insulin at a stable dose and metformin alone 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.