



17 October 2024
EMA/473427/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Yselty

linzagolix choline

On 17 October 2024, 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 Yselty. The marketing authorisation holder for this medicinal product is Theramex Ireland Limited.

The CHMP adopted a new indication to include treatment of patients with endometriosis, as follows:

Yselty is indicated in adult women of reproductive age for:

- symptomatic treatment of endometriosis in women with a history of previous medical or surgical treatment for their endometriosis (see section 5.1).

For information, the full indications will be as follows:²

Yselty is indicated in adult women of reproductive age for:

- treatment of moderate to severe symptoms of uterine fibroids,
- **symptomatic treatment of endometriosis in women with a history of previous medical or surgical treatment for their endometriosis (see section 5.1).**

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 made available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

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

