22 April 2022
EMA/CHMP/223560/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Elonva

corifollitropin alfa

On 22 April 2022, 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 Elonva. The marketing authorisation holder for this medicinal product is Organon N.V.

The CHMP adopted a new indication for the treatment of hypogonadotropic hypogonadism.

For information, the full indications for Elonva will be as follows:[2]

> Elonva is indicated for Controlled Ovarian Stimulation (COS) in combination with a Gonadotropin Releasing Hormone (GnRH) antagonist for the development of multiple follicles in women participating in an Assisted Reproductive Technology (ART) program.
>
> **Elonva is indicated for the treatment of adolescent males (14 years and older) with hypogonadotropic hypogonadism, in combination with human Chorionic Gonadotropin (hCG).**

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.

[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**

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