14 November 2019
EMA/545160/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Isturisa

osilodrostat

On 14 November 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Isturisa[2], intended for the treatment of Cushing's syndrome. The applicant for this medicinal product is Novartis Europharm Limited.

Isturisa will be available as 1-mg, 5-mg and 10-mg film-coated tablets. The active substance of Isturisa is osilodrostat, a cortisol synthesis inhibitor (ATC code: H02CA02). Osilodrostat works by inhibiting 11-beta-hydroxylase (CYP11B1), an enzyme responsible for the final step of cortisol biosynthesis in the adrenal gland.

The benefits with Isturisa are its ability to control or normalise raised cortisol levels. The most common side effects are gastrointestinal disorders, fatigue, headache, oedema and, as the most serious common side effect, adrenal insufficiency.

The full indication is: "Isturisa is indicated for the treatment of endogenous Cushing's syndrome in adults". It is proposed that Isturisa be initiated and supervised by physicians experienced in endocrinology or internal medicine and with access to the appropriate facilities for monitoring of biochemical responses.

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.

[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] This product was designated as orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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