21 July 2022
EMA/CHMP/623061/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lupkynis

voclosporin

On 21 July 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lupkynis, intended for the treatment of lupus nephritis. The applicant for this medicinal product is Otsuka Pharmaceutical Netherlands B.V.

Lupkynis will be available as a 7.9 mg soft capsule. The active substance of Lupkynis is voclosporin, an immunosuppressants (ATC code: L04AD03). Voclosporin is a calcineurin-inhibitor which inhibits lymphocyte proliferation, T-cell cytokine production and expression of T-cell activation surface antigens.

The benefit of Lupkynis is the achievement of a renal response, as evaluated in a phase 3, prospective, randomised, double-blind, study comparing twice daily voclosporin with placebo over a 52-week treatment period. The most common side effects are decreased eGFR and hypertension.

The full indication is:

> Lupkynis is indicated in combination with mycophenolate mofetil for the treatment of adult patients with active class III, IV or V (including mixed class III/V and IV/V) lupus nephritis (LN).

Lupkynis treatment should be initiated and supervised by a qualified physician experienced in the diagnosis and treatment of lupus nephritis.

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

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