12 December 2024
EMA/CHMP/561246/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Nemluvio

nemolizumab

On 12 December 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Nemluvio, intended for the treatment of atopic dermatitis and prurigo nodularis.

The applicant for this medicinal product is Galderma International.

Nemluvio will be available as 30 mg powder and solvent for solution for injection in pre-filled pen or syringe. The active substance of Nemluvio is nemolizumab, an other dermatological preparation, agent for dermatitis, excluding corticosteroids (ATC code: D11AH12). Nemolizumab is a humanised IgG2 monoclonal antibody that inhibits interleukin-31 signalling by binding selectively to interleukin-31 receptor alpha. IL-31 is a cytokine involved in pruritus, inflammation, epidermal dysregulation and fibrosis. By inhibiting IL-31-induced responses, Nemluvio prevents the release of proinflammatory cytokines and chemokines.

The benefits of 16 weeks of treatment with Nemluvio is its ability to improve the skin condition of patients with atopic dermatitis, as measured by improvements in the IGA and EASI-75 scales, and in patients with prurigo nodularis, as measured by improvements in the IGA scale, compared to placebo. Patients with prurigo nodularis also had a reduction in itching, as measured by PP NRS. The most common side effects with Nemluvio in atopic dermatitis and prurigo nodularis are type I hypersensitivity (includes urticaria and angioedema) and injection site reactions. Additional side effects were reported in prurigo nodularis: headache, atopic dermatitis, eczema and eczema nummular.

The full indication is:

> Atopic dermatitis (AD)
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> Nemluvio is indicated for the treatment of moderate-to-severe atopic dermatitis in patients aged 12 years and older who are candidates for systemic therapy.
>
> Prurigo nodularis (PN)

[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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Nemluvio is indicated for the treatment of adults with moderate-to-severe prurigo nodularis who are candidates for systemic therapy.

Treatment with nemolizumab should be initiated and supervised by healthcare professionals experienced in the diagnosis and treatment of conditions for which nemolizumab is indicated.

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.