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Nemluvio (*nemolizumab*)

An overview of Nemluvio and why it is authorised in the EU

What is Nemluvio and what is it used for?

Nemluvio is a medicine used to treat adults and adolescents aged 12 years and older who have atopic dermatitis (also known as atopic eczema, when the skin is itchy, red and dry) or adults with moderate-to-severe prurigo nodularis (a long-term skin disease with a rash causing lumps with intense itching). It can be used when the patient can be treated with systemic treatments (a medicine given by mouth or injection).

Nemluvio contains the active substance nemolizumab.

How is Nemluvio used?

Nemluvio is available as pre-filled pens and pre-filled syringes and is given as an injection under the skin. The medicine can only be obtained with a prescription; treatment should be started and supervised by a healthcare professional who has experience in the diagnosis and treatment of the conditions Nemluvio is used to treat.

For more information about using Nemluvio, see the package leaflet or contact your doctor or pharmacist.

How does Nemluvio work?

The active substance in Nemluvio, nemolizumab, is a monoclonal antibody (a type of protein) designed to attach to and block the action of interleukin 31 (IL-31). IL-31 plays a role in the skin inflammation and itching seen in people with atopic dermatitis and prurigo nodularis. By blocking IL-31, Nemluvio relieves these symptoms.

What benefits of Nemluvio have been shown in studies?

Atopic dermatitis

Nemluvio was more effective than placebo (a dummy treatment) at reducing the extent and severity of atopic dermatitis in two main studies in adults and adolescents aged 12 years and older with moderate-to-severe atopic dermatitis. In both studies, patients for whom topical medication did not work well enough were given Nemluvio or placebo in combination with background therapy, such as

corticosteroid skin creams and moisturisers. The studies measured improvements after 16 weeks in the severity of skin rash as assessed by study investigators, and in the extent and severity of eczema using the eczema area and severity index (EASI).

In the first study, involving 941 patients, Nemluvio was successful at clearing or almost clearing the affected skin in 35.6% (221 out of 620) of patients, compared with 24.6% (79 out of 321) of patients given placebo. In addition, 43.5% (270 out of 620) of patients treated with Nemluvio showed an improvement of at least 75% in disease extent and severity, compared with 29.0% (93 out of 321) of patients given placebo.

In the second study, involving 787 patients, Nemluvio was successful at clearing or almost clearing the affected skin in 37.7% (197 out of 522) of patients, compared with 26.0% (69 out of 265) of patients given placebo. In addition, 42.1% (220 out of 522) of patients treated with Nemluvio showed an improvement of at least 75% in disease extent and severity, compared with 30.2% (80 out of 265) of patients given placebo.

Prurigo nodularis

Nemluvio was more effective than placebo at reducing the severity of itching and skin rash caused by prurigo nodularis in two main studies in adults with moderate-to-severe prurigo nodularis. In both studies, patients were given Nemluvio or placebo. Patients were allowed to continue using moisturisers during the study. The studies measured improvements after 16 weeks in itching severity using the peak pruritus numerical rating scale (PP NRS), which assesses itching severity reported by patients on a scale of 0 (none) to 10 (worst), and in skin rash severity as assessed by study investigators.

In the first study, involving 286 patients, 58.4% (111 out of 190) of patients treated with Nemluvio showed an improvement of at least 4 points in itching severity on the PP NRS, compared with 16.7% (16 out of 96) of patients given placebo. In addition, Nemluvio was successful at clearing or almost clearing the affected skin in 26.3% (50 out of 190) of patients, compared with 7.3% (7 out of 96) of patients given placebo.

In the second study, involving 274 patients, 56.3% (103 out of 183) of patients treated with Nemluvio showed an improvement of at least 4 points on the PP NRS, compared with 20.9% (19 out of 91) of patients given placebo. In addition, Nemluvio was successful at clearing or almost clearing the affected skin in 37.7% (69 out of 183) of patients, compared with 11.0% (10 out of 91) of patients given placebo.

What are the risks associated with Nemluvio?

For the full list of side effects and restrictions with Nemluvio, see the package leaflet.

In people with atopic dermatitis and prurigo nodularis, the most common side effects with Nemluvio (which may affect up to 1 in 10 people) include allergic reactions and injection site reactions. In people with prurigo nodularis, headache, atopic dermatitis and eczema may also occur in up to 1 in 10 people.

Why is Nemluvio authorised in the EU?

Studies showed that Nemluvio provides meaningful improvements in disease symptoms in patients with atopic dermatitis and prurigo nodularis, and side effects were generally mild and manageable. The European Medicines Agency therefore decided that Nemluvio's benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Nemluvio?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Nemluvio have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Nemluvio are continuously monitored. Suspected side effects reported with Nemluvio are carefully evaluated and any necessary action taken to protect patients.

Other information about Nemluvio

Nemluvio received a marketing authorisation valid throughout the EU on 12 February 2025.

Further information on Nemluvio can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/nemluvio.

This overview was last updated in 02-2025.