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Summary report on authorisation dated 10 June 2025

Nemluvio® (active substance: nemolizumab)

Authorisation in Switzerland: 17 February 2025

Pre-filled pen for the treatment of atopic dermatitis and prurigo nodularis

About the medicinal product

Nemluvio contains the active substance nemolizumab and is used to treat adults and adolescents 12 years of age and older weighing at least 30 kg with moderate to severe atopic dermatitis (AD), when the disease is not adequately controlled with topical[1] medicinal products alone. AD, also known as atopic eczema, is an inflammatory skin disease associated with severe itch and dry skin. It often affects children and can persist into adulthood.

Nemluvio is also used to treat adults with moderate to severe prurigo nodularis (PN). PN is a fairly rare, chronic skin condition characterised by severely itchy nodules.

Nemluvio was authorised as part of the joint initiative of the Access Consortium. This joint initiative is a collaborative project between the drug regulatory authorities in Australia (Therapeutic Goods Administration, TGA), Canada (Health Canada, HC), Singapore (Health Sciences Authority, HSA), the United Kingdom (Medicines & Healthcare products Regulatory Agency, MHRA), and Swissmedic and the pharmaceutical industry. The joint initiative coordinates the assessment of authorisation applications for new active substances that have been submitted in at least 2 of the 5 countries.

The authorisation application for Nemluvio was submitted for assessment to the regulatory authorities in Australia, Singapore, the United Kingdom and Switzerland. Each country assessed a part of the application and then shared and discussed the results. At the end of the process, each authority decided on the application independently.

Mode of action

The active ingredient nemolizumab is a protein that acts as a monoclonal antibody to block the effect of a substance known as interleukin-31 (IL-31). This IL-31 is involved in the development of skin inflammation and itching in patients with AD or PN. By blocking IL-31, Nemluvio can help alleviate itching and thereby improve the quality of life of sufferers.

[1] Topical medicinal products: medicines that are applied directly onto the skin.

Administration

Nemluvio is a prescription-only medicine.

The single-use pre-filled pen contains two chambers, one with 30 mg of nemolizumab in powder form and a second chamber with solvent for solution for injection. Turning a knob activates the pen and causes the powder to be dissolved in the solvent. Nemluvio is injected under the skin. In patients with AD, the recommended initial dose for adults and adolescents 12 years of age and older is 60 mg (two 30 mg injections), followed by 30 mg every 4 weeks. After16 weeks, the dosing interval is extended to every 8 weeks, provided a clinical response is observed. In patients with PN, the dose varies according to body weight. After the initial dose of 60 mg, patients weighing less than 90 kg receive 30 mg every 4 weeks, while those weighing 90 kg or more receive 60 mg every 4 weeks. The Nemluvio pens are stored in the refrigerator, protected from light in the carton.

Efficacy

The efficacy of Nemluvio for the treatment of AD was investigated in two studies (ARCADIA 1 and ARCADIA 2). The participants received either Nemluvio (1192 subjects) or a placebo (dummy drug) (640 subjects) for 16 weeks in combination with topical medications[1]. The primary endpoints were the percentage of patients with IGA[2] success (reduction in the severity score to 0 or 1) and a 75% improvement in the EASI score[3]. The results showed that Nemluvio was significantly more effective than placebo, producing a clinically relevant effect.

The efficacy of Nemluvio as monotherapy (single dose) for PN was investigated in two studies (OLYMPIA 1 and OLYMPIA 2).The patients received either Nemluvio (370 subjects) or a placebo (186 subjects) over a period of 16 weeks. The main endpoints of the studies were the improvement in itching (determined by a reduction in the PP-NRS[4] score of 4 or more points) and the clinical success of the treatment (measured by a reduction in the IGA score[2] to 0 or 1). The results showed that Nemluvio was significantly better than placebo, producing a clinically relevant effect.

Precautions, undesirable effects, & risks

Nemluvio must not be used in those who are hypersensitive to the active substance or any of the excipients.

Common undesirable effects include headache, nettle rash and eczema (atopic dermatitis).

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

[2] IGA (Investigator Global Assessment) is an assessment by the doctor to determine the current severity of the skin condition – from 0 "clear" to 4 "severe".

[3] EASI score (Eczema Area and Severity Index) is an assessment tool used by the doctor to estimate the severity and extent of the skin changes in atopic dermatitis,resulting in a total score ranging from 0 (no change) to 72 (very severe disease).

[4] PP-NRS (Peak Pruritus Numerical Rating Scale) is a simple scale from 0 to 10, where the patient reports the severity of the worst itch in the last 24 hours – 0 means "no itch", 10 stands for "worst itch imaginable".

Why the medicinal product has been authorised

AD and PN are serious skin diseases that cause very unpleasant symptoms such as severe itching. The treatment options available to date have been limited, particularly for PN. Nemluvio, containing the active substance nemolizumab, showed a promising effect in alleviating the symptoms of the disease. A significant improvement in itching and skin condition was observed in patients taking part in clinical trials. Taking all the risks and precautions into account, and based on the available data, the benefits of Nemluvio outweigh the risks. Swissmedic has therefore authorised the medicinal product Nemluvio, containing the active substance nemolizumab, for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Nemluvio®

Information for patients (package leaflet): Information for patients Nemluvio®
Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.