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Nemluvio® (nemolizumab) media factsheet

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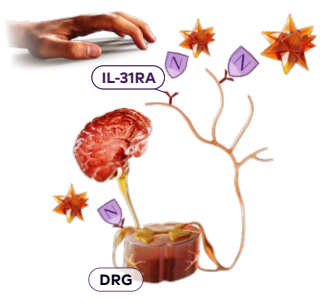
What is Nemluvio?

Nemluvio is the first approved monoclonal antibody for atopic dermatitis and prurigo nodularis that specifically targets IL-31 receptor alpha (IL-31RA), inhibiting the signaling of IL-31.[1-3]

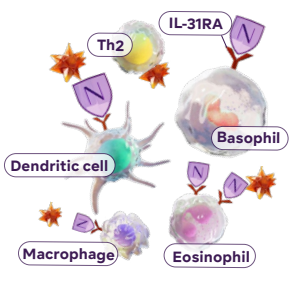
IL-31 is a neuroimmune cytokine that drives itch and is involved in inflammation and epidermal dysregulation in both atopic dermatitis and prurigo nodularis and in fibrosis in prurigo nodularis.[1,4-6]

Targeting and blocking IL-31 activity has been shown to rapidly and effectively address the symptoms and pathophysiology of both diseases:[1-3,7-9]



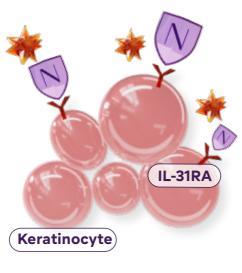
Itch

Nemluvio blocks the IL-31 signaling taking place uniquely on the dorsal root ganglion (DRG) that drives neuronal activation, elongation, and branching, which triggers the itch sensation and scratch.[1]



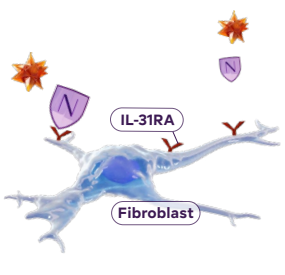
Inflammation

Nemluvio blocks IL-31RA overexpression on basophils, eosinophils, macrophages, and dendritic cells to calm inflammation.[5,6]



Skin Barrier Dysfunction

Nemluvio blocks IL-31RA from interfering with keratinocyte differentiation to restore the skin barrier.[1,6]



Fibrosis

Nemluvio blocks IL-31RA from stimulating fibroblasts, helping to prevent collagen deposition, tissue remodeling, and fibrosis.[1,2]

Value of Nemluvio in the current treatment landscape

Nemluvio has the potential to address the significant unmet needs of patients with prurigo nodularis and moderate-to-severe atopic dermatitis:[7-13]

Robust results from the phase III OLYMPIA and ARCADIA clinical trial programs have shown its ability to significantly improve **itch, skin lesions and sleep disturbance.**[7-9]

Post-hoc analyses have shown a significant improvement in itch and sleep disturbance as early as **two days** after treatment initiation in some patients.[10]

Nemluvio has also demonstrated **continued improvements over time** on skin, itch and quality of life up to two years for atopic dermatitis and up to three years for prurigo nodularis.[11-12]

Nemluvio was **well tolerated** in all trials, and its safety profile was generally consistent between trials.[1,7-9]

Nemluvio is administered **subcutaneously** (under the skin) and is available as a **pre-filled pen** that can be stored at room temperature for up to 90 days, offering patients and healthcare professionals a **convenient treatment option**.[2,3,13]

It is the first and only biologic approved for atopic dermatitis and prurigo nodularis with **four-week dosing intervals** from the start of treatment.[2,3]

In atopic dermatitis, Nemluvio is the first and only treatment to offer patients who achieve a stable clinical response the option to transition to dosing **every eight weeks**, potentially reducing the burden of treatment.[2,3]

Nemluvio does not require preliminary laboratory **evaluations** or **monitoring** during treatment.[2,3]

Nemluvio is a much-needed new treatment option for atopic dermatitis and prurigo nodularis. It offers a novel mechanism of action, and its extensive body of evidence has shown it acts quickly on itch, often reported as one of the most burdensome symptoms, and has a positive effect on skin lesions and sleep disturbance. It's also a convenient option for both patients and healthcare professionals – being available as a pre-filled pen with four-week dosing intervals, which can be reduced to every eight weeks in atopic dermatitis.

Professor Diamant Thaçi
Lead Investigator of the ARCADIA studies in Europe
University of Lubeck, Germany

Nemluvio is **approved** for both moderate-to-severe atopic dermatitis and prurigo nodularis in **multiple countries and regions**, including the United States and European Union.[2,3] It is under review for the treatment of both diseases by several additional regulatory authorities around the world. Further submissions to regulatory authorities in additional countries are ongoing.

Nemluvio is the **first biologic** in Galderma's Therapeutic Dermatology portfolio, and just one example of our innovative, science-based pipeline with products that span the full spectrum of the fast-growing dermatology market through Injectable Aesthetics, Dermatological Skincare and Therapeutic Dermatology.

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