nemluvio™
(nemolizumab-ilto) for injection
30 mg

Electronic Health Record (EHR)

Instructions to Create a Protocol for Adults With Prurigo Nodularis (PN) With NEMLUVIO® in the EMA® EHR System

IMPORTANT SAFETY INFORMATION

INDICATION: NEMLUVIO is an interleukin-31 receptor antagonist indicated for the treatment of adults with prurigo nodularis.

Please see Important Safety Information on page 7 and accompanying Prescribing Information or click here for full Prescribing Information.

EMA, Electronic Medical Assistant.

Background, Instructions, and Limitations

Indication

NEMLUVIO is indicated for the treatment of PN.[1]

Limitations of Use

These instructions were created specifically to update a protocol in the EMA EHR system and will not work in other EHR systems. These instructions are designed to be used for NEMLUVIO for the treatment of PN and should not be used for other conditions, treatments, or therapeutic areas.

The processes outlined in this piece are variable and not all steps will apply to every health system. Any steps or settings that are not part of a health system's standard process should be excluded or modified accordingly. Any questions should be directed to the appropriate service provider. The practice is solely responsible for implementing, testing, monitoring, and ongoing operation of any EHR tools.

A health system may choose to optimize existing EHR protocols or to create a new protocol for NEMLUVIO. Protocols consolidate notes, referrals, imaging studies, lab orders and bundles, medications, patient education, coding and billing information, and other orderable items used to manage a condition or problem. Protocols can improve the user experience and help reduce practice variation. These instructions detail specifically how to add the initiation and maintenance dosing of NEMLUVIO to protocols.

EHR, electronic health record; EMA, Electronic Medical Assistant; PN, prurigo nodularis.

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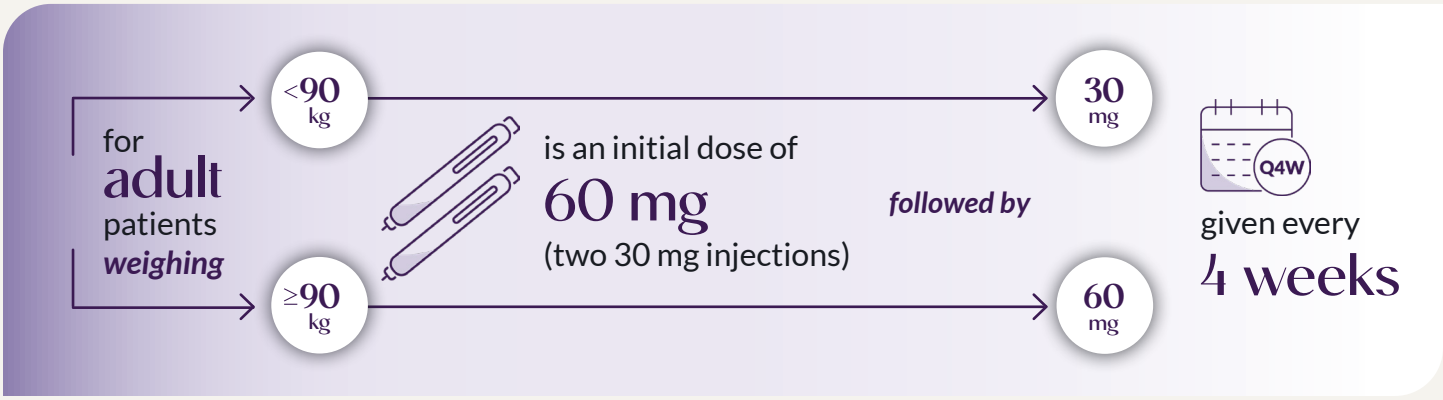
Recommended Subcutaneous Dosage of NEMLUVIO for PN[1]:



Complete all age-appropriate vaccinations as recommended by current immunization guidelines prior to treatment with NEMLUVIO [*see Warnings and Precautions (5.2)*].[1]

Review the NEMLUVIO Prescribing Information for additional information, including important administration instructions, preparation for use of NEMLUVIO, missed dose information, and additional information.

Mechanism of Action

- NEMLUVIO is a humanized IgG2 monoclonal antibody that inhibits IL-31 signaling by binding selectively to IL-31RA[1]
- IL-31 is a naturally occurring cytokine that is involved in pruritus, inflammation, epidermal dysregulation, and fibrosis[1]
- NEMLUVIO inhibited IL-31-induced responses, including the release of proinflammatory cytokines and chemokines[1]

IgG, immunoglobulin G; IL-31RA, interleukin-31 receptor alpha; PN, prurigo nodularis.

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EMA Instructions

EMA comes with a wide range of dermatology-specific protocols. New protocols may be created by the user and shared with other clinicians within the practice. Since NEMLUVIO has an initiation and maintenance dosing (every 4 weeks [Q4W]), consider creating 2 separate plans or protocols for NEMLUVIO if this approach is aligned with your governing EHR plan conventions and builds.

1. Open the web version of EMA
2. Click Preferences (in the top-right corner of the window) and select Manage Protocols
3. Search for existing protocols in the system. Click the tab to toggle between My Protocols and Practice Protocols
4. Click Add Protocol
5. Complete the Protocol information by entering a unique title, for example “NEMLUVIO initiation for prurigo nodularis” and “NEMLUVIO maintenance for prurigo nodularis”. Consider adding keywords “prurigo nodularis” to help users searching for Protocols
6. Under Shared with Everyone in Firm, select the Yes radio button to make the protocol available to other users in the practice
7. Any desired items can be added to the Protocol. Consider the Exam Set, Diagnosis, Location, etc., as desired
8. Click Save. The Virtual Exam Room will open to complete the Protocol

Instructions continued on the next page.

EHR, electronic health record; EMA, Electronic Medical Assistant.

EMA Instructions (cont'd)

9 In the Plans section, select Prescription, then Find Other Medication, search for and select NEMLUVIO. Add the NEMLUVIO medication details

For the NEMLUVIO initiation for PN plan, complete the medication details below:

- Adult patients weighing less than 90 kg: The recommended initial dosage of NEMLUVIO for adult patients weighing less than 90 kg is an initial dose of 60 mg (two 30 mg injections)[1]
- Adult patients weighing 90 kg or more: The recommended initial dosage of NEMLUVIO for adult patients weighing 90 kg or more is an initial dose of 60 mg (two 30 mg injections)[1]

For the NEMLUVIO maintenance for PN plan, complete the medication details below:*

- Adult patients weighing less than 90 kg: The recommended maintenance dosage of NEMLUVIO for adult patients weighing less than 90 kg is 30 mg given every 4 weeks (Q4W)[1]
- Adult patients weighing 90 kg or more: The recommended maintenance dosage of NEMLUVIO for adult patients weighing 90 kg or more is 60 mg given Q4W[1]

In the Counseling section, consider adding:

10

The hyperlink to the current NEMLUVIO PI (which includes the NEMLUVIO recommended vaccinations prior to treatment initiation, dosage and administration, warnings and precautions, and adverse reactions): https://www.galderma.com/sites/default/files/2024-08/Nemluviouspippi0812.pdf

The hyperlink and QR code accessing the NEMLUVIO enrollment form. Note: the patient enrollment form has 2 prescriptions on the bottom of the form (for quick start and regular prescription): https://www.nemluviohcp.com/pdf/enrollment-form.pdf

The hyperlink to the NEMLUVIO patient savings card for Commercial patients: https://www.GaldermaHCPPortal.com

NEMLUVIO has a limited distribution network and is available at: https://www.nemluviohcp.com/pdf/specialty-pharmacy-facts.pdf

EMA, Electronic Medical Assistant; PI, Prescribing Information; PN, prurigo nodularis.
*Maintenance dosing starts 4 weeks after initial dose.[1]

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EMA Instructions (cont'd)

11 Click Done at the bottom of the prescription to save the medication details

12 In the Follow Up section, set any follow-up appointments as desired

13 Click Save Visit Protocol

Notes

The customers (ie, physician, medical group, integrated delivery network) shall be solely responsible for implementation, testing, and monitoring of the instructions to ensure proper orientation in each customer's EHR system.

Capabilities, functionality, and setup (customization) for each EHR system may vary. Galderma shall not be responsible for revising the implementation instructions it provides to any customer if the customer modifies or changes its software, or the configuration of its EHR system, after such time as the implementation instructions have been initially provided by Galderma.

While Galderma tests its implementation instructions on multiple EHR systems, the instructions are not guaranteed to work for all available EHR systems and Galderma shall have no liability thereto.

While EHRs may assist providers in identifying appropriate patients for consideration of assessment, treatment, and referral, the decision and action should ultimately be decided by a provider in consultation with the patient after a review of the patient's records to determine eligibility, and Galderma shall have no liability thereto.

The instructions have not been designed to and are not tools and/or solutions for meeting Advancing Care Information and/or any other quality/accreditation requirement.

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Important Safety Information

INDICATION: NEMLUVIO is an interleukin-31 receptor antagonist indicated for the treatment of adults with prurigo nodularis.

CONTRAINDICATION: NEMLUVIO is contraindicated in patients with known hypersensitivity to nemolizumab-ilto or to any of the excipients in NEMLUVIO.

WARNINGS AND PRECAUTIONS:
Hypersensitivity reactions have been reported with NEMLUVIO use. If clinically significant hypersensitivity reaction occurs, immediately institute appropriate therapy, and discontinue NEMLUVIO. Avoid use of live vaccines during treatment with NEMLUVIO.

ADVERSE REACTIONS:
Most common adverse reactions (incidence ≥1%) are headache, dermatitis atopic, eczema, and eczema nummular.

USE IN SPECIFIC POPULATIONS:
Pregnancy: There are no adequate and well-controlled studies on NEMLUVIO in pregnant women. The limited available information on NEMLUVIO use during pregnancy is not sufficient to inform a drug-associated risk of major birth defects or miscarriage in humans. Human IgG antibodies are known to cross the placental barrier; therefore, NEMLUVIO may be transmitted from the mother to the developing fetus.

Lactation: There are no data on the presence or transfer of NEMLUVIO in human milk, the effects on the breastfed infant, or the effects on milk production. Human IgG is known to be present in human milk. The effects of local gastrointestinal and limited systemic exposure to NEMLUVIO on the breastfed infant are unknown. NEMLUVIO has not been administered to nursing/lactating women. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for NEMLUVIO and any potential adverse effects on the breastfed child from NEMLUVIO or from the underlying maternal condition.

Please see accompanying Prescribing Information or click here for full Prescribing Information.