NEXTSTEPS IN DERM | GW School of Medicine & Health Sciences

Nemolizumab Therapeutic Cheat Sheet

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TRADE NAME

- Nemluvio

MECHANISM OF ACTION[12-17]

- Interleukin-31 antagonist: binds IL-31 cytokine, preventing interaction with its receptor, IL-31RA, and therefore, all biological activity of this cytokine.
  - Pruritus in atopic dermatitis and prurigo nodularis is largely driven by type-2 immunity, including what is being called the itch cytokine, IL-31
  - The concentration of IL-31 is significantly increased in lesional skin compared to controls in patients with atopic dermatitis and prurigo nodules

FDA APPROVED FOR[14-15]

- Moderate-to-severe atopic dermatitis
- Prurigo Nodularis

OFF-LABEL DERMATOLOGIC USES[6,11,12]

- Generalized pruritus
- Uremic pruritus
- Lichen simplex chronicus
- Macular/Lichen Amyloidosis

DOSING (SUBCUTANEOUS INJECTION)[12-17]

- Prurigo nodularis dosing:
  - Adult patients weighing less than 90kg:
    - Initial dose of 60 mg (two 30 mg injections) followed by 30 mg (one 30 mg injection) every four weeks
  - Adult patients weighing more than 90kg:
    - Initial dose of 60 mg (two 30 mg injections) followed by 60 mg (two 30 mg injections) every four weeks
- Atopic dermatitis dosing:
  - For adults and adolescents aged 12 years and older:
    - Initial dose of 60 mg (two 30 mg injections) followed by 30 mg (one 30 mg injection) every four weeks

ADMINISTRATION[12-17]

- Patients should be brought up to date with all vaccinations prior to initiating therapy with nemolizumab
- Nemolizumab must be reconstituted prior to administration:
  - Remove from refrigerator and allow to reach room temperature (30-45 minutes), nemolizumab is safe at room temperature for 90 days unless reconstituted, if so, it must be used within four hours
  - Inspect dual chamber, do not use if powder is not white or dilutant is cloudy or has visible particles
  - Turn the activation knob at the bottom to the right until it stops (towards the unlock icon), this will start the reconstitution
  - Shake the pen up and down for thirty seconds, wait five minutes for bubbles to decrease and powder dissolved, consider shaking again for thirty seconds and wait another five minutes for bubbles to decrease if needed
  - Twist the gray cap, do not pull, until the orange needle guard pops up and remove gently
  - Place pen perpendicular to injection site, anterior thigh or abdomen, deltoid only if by caregiver, apply pressure until the orange needle guard is pushed inward, a click should be heard, hold for 15 seconds, lift the pen up vertically and place in sharps container, cotton ball or gauze for injection site bleeding

SIDE EFFECTS[8,9,10]

- Neurological: Headache
- Cutaneous: Hypersensitivity reactions (angioedema), new onset or exacerbated atopic dermatitis, eczema, nummular dermatitis, bullous pemphigoid, asthma
- Respiratory: nasopharyngitis, upper respiratory tract infection
- Musculoskeletal: elevated creatine kinase and peripheral edema

DRUG INTERACTIONS[14,15]

- Nemolizumab may decrease serum concentration of cytochrome P450 (CYP450) substrates: upon initiation or discontinuation of nemolizumab, consider monitoring for effect or drug concentration and consider dosage modification (e.g., warfarin, cyclosporine, etc.)
- Nemolizumab may diminish the therapeutic effect of Fc receptor binding agents such as efgartigimod alfa and rozanolixizumab

CONTRAINDICATIONS[12,14,15]

- Known hypersensitivity to nemolizumab or to any of the excipients in nemolizumab
- Avoid use of live vaccines

PREGNANCY AND BREASTFEEDING[12,14,15]

- Available data on nemolizumab use in pregnant women exposed in clinical trials are insufficient to evaluate for drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes
- Transport of IgG antibodies across the placenta increase during pregnancy, therefore nemolizumab may be transferred to a developing fetus
- There is no data on the presence of nemolizumab in human milk, the effects on the breastfed infant, or effects on milk production, nemolizumab has been noted in the milk of monkeys after exposure

MONITORING[12,14,15]

- No lab monitoring required

INSURANCE COVERAGE (ALL CRITERIA MUST BE MET)[1-5,7,18,19]

- Atopic Dermatitis:
  - Diagnosis of moderate-to-severe AD
  - Prescribed by or in consultation with a specialist, such as a dermatologist, allergist, or immunologist
  - At least 10% body surface area involvement
  - History of failure, contraindication, or intolerance to previous AD treatment(s), such as topical corticosteroids, topical calcineurin inhibitors, or a topical PDE4 inhibitor
  - Patient is not receiving nemolizumab in combination with another biologic immunomodulator or JAK inhibitor
- Prurigo Nodularis:
  - Diagnosis of prurigo nodularis (PN)
  - Prescribed by or in consultation with a specialist, such as a dermatologist, allergist, or immunologist
  - 20 or more PN lesions
  - Pruritus duration for ≥6 weeks
  - History of failure, contraindication, or intolerance to previous PN treatment(s), such as phototherapy, topical corticosteroids, topical calcineurin inhibitors, methotrexate, or cyclosporine
  - Patient is not receiving nemolizumab in combination with another biologic immunomodulator

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