Soothe Itchy Skin With Numelvi

Numelvi™
(atinvicitinib tablets)

If your dog suffers from itch caused by skin allergies, ask your veterinarian about Numelvi™ (atinvicitinib tablets).

Here's what to know about Numelvi.

- **Absorbed quickly** to start relieving allergic itch within 2-4 hours[1]*
- **Easy dosing**, given once daily with food at or around mealtime
- **Proven safe and effective** in clinical studies
- **Can be used** with other common treatments and vaccines†

* In a canine interleukin-31 (cIL-31)-induced pruritus model.

† No clinically relevant drug interactions were observed during a 28-day field trial in dogs with allergic dermatitis when used with antimicrobials (including topicals), ecto- and endoparasiticides (isoxazolines, milbemycins, avermectins, pyrethrins, and pyrethroids), analgesics, anesthetics, nutritional supplements, and topical skin and ear cleansers that did not contain glucocorticoids, as well as medicated shampoos.

Tackling Your Dog's Itch

Skin allergies happen when your dog's immune system reacts to allergens. Quick treatment is important, and some dogs may need lifelong care. Follow these tips to help manage your dog's itch:

1. **Partner With Your Veterinarian.**
   Allergic dermatitis can be a lifelong condition, but there are ways to help manage it.
2. **Stick With the Plan.**
   Each dog is unique, so pay attention to what may or may not be working for your pet.
3. **Stay in Touch.**
   Together with your veterinarian, you can use these insights to build a treatment plan that keeps your dog feeling their best.

Important Safety Information

NUMELVI is not for use in dogs less than 6 months of age or those with serious infections. NUMELVI may increase susceptibility to opportunistic infections, including demodicosis and interdigital furunculosis. Consider the risks and benefits of treatment prior to initiating NUMELVI in dogs with a history of recurrent demodicosis. NUMELVI is a JAK inhibitor. New neoplastic conditions (benign and malignant) have been reported in dogs treated with other JAK inhibitors. The effectiveness and safety of NUMELVI have not been evaluated in a field study beyond 28 days. The safe use of NUMELVI has not been evaluated in breeding, pregnant, or lactating dogs, nor in combination with glucocorticoids, cyclosporine, or other systemic immunosuppressive agents. For complete safety information, refer to the product label.

Visit
fixmydogsitch.com
for helpful resources

Numelvi™ (atinvicitinib tablets)

223751 R10

Immunomodulator

For oral use in dogs only

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION:
The active ingredient in NUMELVI is atinvicitinib. Atinvicitinib is a synthetic selective Janus kinase (JAK) 1 inhibitor. The chemical (IUPAC) name of atinvicitinib is 1-[(3R,4S)-4-cyanooxan-3-yl]-3-[[2-fluoro-6-methoxypyridin-4-yl]amino]-1H-pyrazole-4-carboxamide.

INDICATIONS:
NUMELVI is indicated for the control of pruritus associated with allergic dermatitis in dogs 6 months of age and older.

WARNINGS:
User Safety Warnings:
This product is not for human use. Keep this and all drugs out of reach of children. Wash hands thoroughly with soap and water immediately after handling tablets. In case of accidental ingestion, seek medical attention immediately.

Animal Safety Warnings:
Dogs should be monitored for the development of infections because NUMELVI may increase susceptibility to opportunistic infections, including demodicosis and interdigital furunculosis (see **Target Animal Safety**).

NUMELVI is not for use in dogs with serious infections.

NUMELVI is a JAK inhibitor. New neoplastic conditions (benign and malignant) have been reported in dogs treated with other JAK inhibitors.

Consider the risks and benefits of treatment prior to initiating NUMELVI in dogs with a history of recurrent demodicosis.

NUMELVI modulates the immune system.

NUMELVI is not for use in dogs less than 6 months of age (see **Target Animal Safety**).

Keep NUMELVI in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

PRECAUTIONS:
The effectiveness and safety of NUMELVI have not been evaluated in a field study beyond 28 days (see **Adverse Reactions** and **Effectiveness**).

The safe use of NUMELVI has not been evaluated in breeding, pregnant, or lactating dogs. Decreased mean testes weight was observed in a laboratory safety study (see **Target Animal Safety**).

The safe use of NUMELVI has not been evaluated in combination with glucocorticoids, cyclosporine, or other systemic immunosuppressive agents.

ADVERSE REACTIONS:
In a masked field study assessing effectiveness and safety of NUMELVI for the control of pruritus associated with allergic dermatitis in dogs, 144 NUMELVI-treated dogs and 144 placebo-treated dogs were evaluated for safety for up to 28 days. Adverse reactions seen during the field study are summarized in Table 1 below.

Table 1. Adverse Reactions through Day 28

Adverse Reaction	NUMELVI (N=144) Number of dogs (%)	Placebo (N=144) Number of dogs (%)
Vomiting or nausea	10 (6.9%)	6 (4.2%)
Otitis externa	9 (6.3%)	8 (5.6%)
Hematuria (without urinary tract infection)	7 (4.9%)	6 (4.2%)
Anorexia	6 (4.2%)	5 (3.5%)
Bacterial skin infection	6 (4.2%)	10 (6.9%)
Diarrhea	6 (4.2%)	15 (10.4%)
Crystalluria	5 (3.5%)	2 (1.4%)
Lethargy	5 (3.5%)	5 (3.5%)
Urinary tract infection	5 (3.5%)	5 (3.5%)
Upset stomach, including flatulence, retching, and bloating	3 (2.1%)	0
Neurological disorder (e.g., tremors, ataxia)	2 (1.4%)	1 (0.7%)
Ocular discharge	2 (1.4%)	1 (0.7%)
Coughing	1 (0.7%)	0
Granuloma	1 (0.7%)	0
Increased urination	1 (0.7%)	0

Abnormal hematology results likely related to NUMELVI administration included leukopenia, neutropenia, eosinopenia, monocytopenia, and lymphocytosis.

Abnormal serum chemistry results likely related to NUMELVI administration included increased alanine aminotransferase (ALT), aspartate aminotransferase (AST), and symmetric dimethylarginine (SDMA), and hypercholesterolemia.

Three NUMELVI-treated dogs withdrew from the study early due to an adverse reaction, two of which were considered likely related to NUMELVI treatment (i.e., diarrhea). Two placebo-treated dogs also withdrew from the study early due to an adverse reaction (i.e., diarrhea).

CONTACT INFORMATION:
For technical information or to report a suspected adverse event, please contact Merck Animal Health at 1-800-224-5318 or https://www.merck-animal-health-usa.com. Safety Data Sheets (SDSs) can be found at https://www.merck.com/products/safety-data-sheets/#.

For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS or https://www.fda.gov/reportanimalae.

EFFECTIVENESS:
A masked, 28-day, placebo-controlled study was conducted at 26 veterinary clinics in the US, enrolling 288 client-owned dogs diagnosed with allergic dermatitis and having at least moderate pruritus. The allergic dermatitis was attributed to one or more of the following conditions (in the order of frequency): atopic dermatitis, unspecified allergic dermatitis, food hypersensitivity, flea allergy dermatitis, and contact dermatitis. Dogs were randomized to once daily treatment with NUMELVI at 0.8 - 1.2 mg/kg or placebo, at a ratio of 1:1 respectively. Other medications that could affect the evaluation of effectiveness were not allowed during the study, such as corticosteroids, antihistamines, and cyclosporine. Treatment success for each dog was defined as a ≥ 50% reduction from baseline in owner-assessed pruritus scores on the Pruritus Visual Analog Scale (PVAS) on at least 5 out of the first 7 days of treatment. The proportion of dogs in the NUMELVI group that were treatment successes was greater than and significantly different compared to the placebo group on Day 7 (Table 2, below).

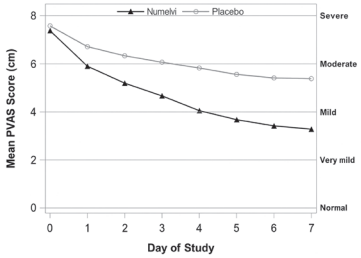
Table 2. Estimated Proportion of Dogs Achieving Treatment Success

Treatment Group	Estimated Proportion of Success*
NUMELVI (N = 125)	0.23
Placebo (N = 125)	0.07†

* Based on back-transformed least squares means.
† Placebo vs. NUMELVI p = 0.0128
N = number of dogs

Mean owner-assessed PVAS scores were lower in the NUMELVI group after Day 0 (Figure 1, below).

Figure 1: Mean owner-assessed PVAS Scores by Treatment for Days 0-7



Veterinarians used a Dermatitis Visual Analog Scale (DVAS) to assess each dog's dermatitis. Veterinarian-assessed DVAS scores were lower for the NUMELVI group compared to the placebo group at all time points through Day 28.

STORAGE CONDITIONS:
NUMELVI tablets should be stored at 15 to 30°C (59 to 86°F).

HOW SUPPLIED:
NUMELVI (atinvicitinib tablets) is available in scored tablets in four strengths: 4.8 mg, 7.2 mg, 21.6 mg, and 31.6 mg per tablet. Each tablet strength is available in 30 and 90 count bottles. Each tablet is marked with an S, M, L, or XL that correspond to the different tablet strengths.

Approved by FDA under NADA # 141-596

Formulated in Austria.
Distributed by Intervet Inc. (d/b/a Merck Animal Health), Rahway, NJ 07065.

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The risk information provided here is not comprehensive. To learn more about Numelvi™, talk with your veterinarian. The FDA-approved product labeling can be found by scanning the QR code or by calling Customer Service at 1-800-521-5767.

Learn More at fixmydogsitch.com

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Customer Service: 1-800-521-5767 | Monday - Friday, 9:00AM - 6:00PM ET

Scan to visit fixmydogsitch.com

Reference: 1. Kowalski T, Prohaczik A, Locke K, et al. The second-generation Janus kinase inhibitor atinvicitinib significantly reduces pruritus 2-4 hours after dosing dogs in a canine interleukin-31 model. *Vet Dermatol.* 2026;0:17-18. https://doi.org/10.1111/vde.70046

MERCK Animal Health

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