Sponsored by Elanco

Managing Canine Allergic Dermatitis With Janus Kinase Inhibitors

Dermatitis is a common presenting complaint in small animal veterinary practice. Atopy, which is just one potential cause of canine allergic dermatitis, is estimated to affect 3% to 15% of dogs, with considerable variation among studies.[1] Other conditions such as contact dermatitis, food allergies, and flea-allergic dermatitis further contribute to the prevalence of allergic dermatitis in dogs.

Veterinarians have multiple options available to manage the clinical signs of allergic dermatitis, including oral, injectable, and topical treatments. Each of these treatments comes with its own unique advantages and disadvantages. Individual patient responses may vary, and finding an effective management plan for an individual patient may prove challenging.

In September of 2024, the US FDA approved a medication for the treatment of canine allergic dermatitis: Zenrelia™ (ilunocitinib tablets). This Janus kinase (JAK) inhibitor blocks the signaling pathway involved in cytokine production, reducing skin inflammation and itch. Zenrelia offers veterinarians an additional treatment to add to their toolkit when managing allergic dermatitis in dogs.

Before prescribing this drug, clinicians should read the entire package insert, including the boxed warning regarding fatal vaccine-induced disease and inadequate immune response to vaccines. It is important that dogs are up to date on vaccinations and free from serious infections prior to starting Zenrelia. Explore this case series highlighting dogs that have experienced improved quality of life after treatment with Zenrelia.

Zenrelia Applications: A Case Series

River's Case

River is a middle-aged German shorthaired pointer. At the time River started receiving Zenrelia, his itch score was determined to be 7.2/10 on the Pruritus Visual Analog Scale (PVAS). This was significantly above the 2/10 PVAS score that is

expected for a clinically normal dog.[2] After just 1 week of receiving Zenrelia, River's PVAS score decreased to 4/10 and continued to decrease to 1.4/10 in the coming weeks, which is below the 2/10 threshold at which a patient is considered to be in remission.

River did experience a slight increase in itch during the peak of spring allergy season; however, even during this time, his PVAS score peaked at 1.8/10. At the end of peak allergy season, River's PVAS score decreased to 1.2/10 and remained at that level in the following months.

Hunter's Case

Hunter is an 8-year-old male Labrador retriever with a history of chronic dermatitis (***Figure 1***). His dermatitis was first noted at 1 to 2 years of age and gradually progressed over time, eventually causing significant impacts on Hunter's quality of life. Hunter chewed the fur from his distal hindlimbs, and his front paws were chronically inflamed and crusty. Hunter's owner tried a variety of treatments; although some treatments offered partial relief, his dermatitis was never well-controlled. Hunter's owner felt defeated and discouraged by his constant skin issues and lack of response to treatment.

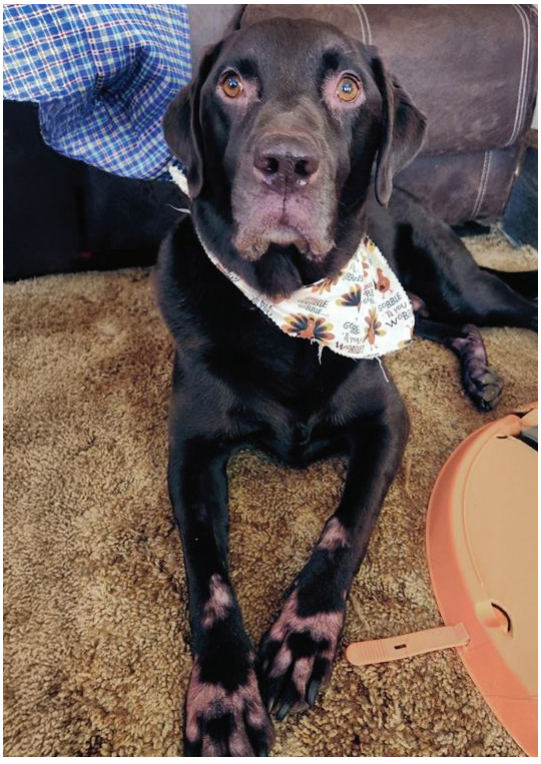


FIGURE 1 Hunter before starting treatment with Zenrelia

Once Zenrelia became available, Hunter's veterinarian prescribed it for Hunter's allergic dermatitis. Hunter responded better to Zenrelia than he had to any previous medications. His clinical signs, including pruritus, paw licking/chewing, and secondary infections, improved dramatically with Zenrelia (***Figures 2*** and ***3***). Hunter's overall quality of life also improved, and his owner reported that he was more comfortable and more playful than he had been prior to Zenrelia treatment.

Scrappy's Case

Scrappy is a male Yorkshire terrier crossbreed. Since his adoption, Scrappy had a history of chronic itching and hot spots. Scrappy's owner felt that he was often "miserable" and unable to get comfortable because of his skin issues. This left the client feeling frustrated and hopeless.

A veterinary dermatologist recommended Zenrelia to treat Scrappy's chronic dermatitis. Scrappy's owner noticed a difference soon after treatment started. At Scrappy's 8-week recheck, the veterinary dermatologist noted marked improvement in Scrappy's dermatitis. He had visible hair regrowth, no visible skin inflammation, and no evidence of secondary infection. Scrappy's owner was very pleased with his progress, reporting that he was no longer chewing and that Zenrelia had worked better than she expected.

Remi & Missy: 2 Housemates

Remi, a Dalmatian, and Missy, a crossbreed dog, live in the same household. Remi had a long-term history of allergic dermatitis, beginning when she was 1 to 2 years of age. Her owner tried a variety of prescription and over-the-counter treatments, but they typically resulted in minimal improve-

ment. Missy's itch started ≈1 year prior to presentation. She was itching and chewing constantly, especially on her legs and tail. Like Remi, Missy was diagnosed with allergic dermatitis.

A veterinary dermatologist recommended starting both Remi and Missy on Zenrelia to treat their allergic dermatitis. At their 2-month recheck, both Remi and Missy showed significant improvement. The client reported that both dogs were responding well to the medication, with no signs of itch observed between doses. On recheck examination, Missy did not have any visible skin lesions, and the veterinary dermatologist found no evidence of itch or inflammation. Remi's dermatitis also improved dramatically on Zenrelia. This was especially remarkable to both the veterinary dermatologist and the client, given Remi's long history of previous treatment failures.

Zenrelia: A Treatment for Canine Allergic Dermatitis

Zenrelia is approved to manage itch caused by atopic dermatitis, contact allergies, food allergies, and flea-allergic dermatitis in dogs ≥12 months of age. In a study of 268 client-owned dogs across 25 veterinary clinics, 83% of dogs achieved treatment success (defined as a ≥50% decrease in client-reported PVAS scores or ≥50% decrease in veterinarian-documented skin lesions) by day 28 of treatment.[3]

Unlike the other currently available JAK inhibitor, Zenrelia is designed for once-daily administration from onset of treatment, which can help improve client compliance.[4] Once-daily administration from the outset also helps avoid rebound pruritus that can occur with medications that require an initial loading dose followed by a dose reduction.[5]

Zenrelia's safety has been demonstrated in a margin of safety study.[6] Healthy dogs treated with up to 5× the label dose for 6 months demonstrated no serious adverse effects. However, Zenrelia should not be used in dogs with serious underlying

FIGURE 2 Hunter 2 weeks after starting treatment with Zenrelia

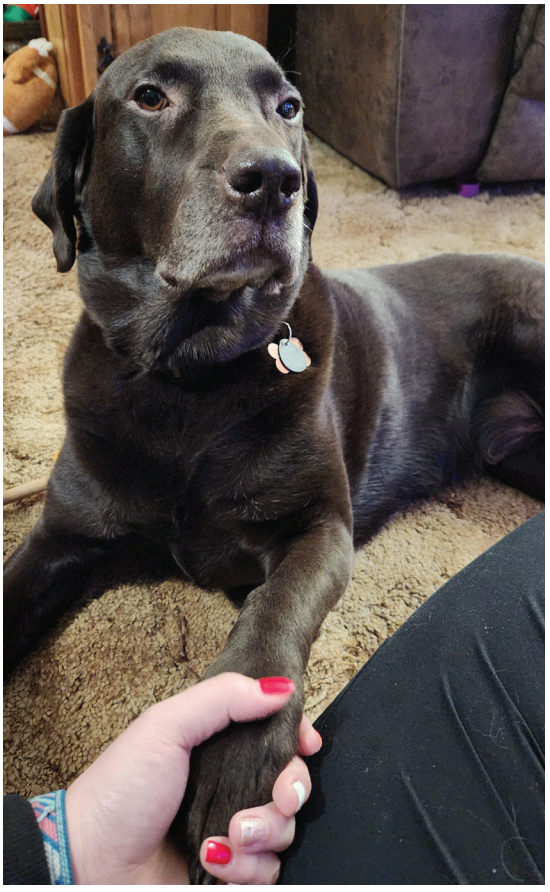


FIGURE 3 Hunter 2 months after starting treatment with Zenrelia

Article continues on page 6 ▶

JAK = Janus kinase

PVAS = Pruritus Visual Analog Scale

INDICATIONS
Zenrelia is indicated for control of pruritus associated with allergic dermatitis and control of atopic dermatitis in dogs at least 12 months of age.

IMPORTANT SAFETY INFORMATION
Read the entire package insert before using this drug, including the Boxed Warning.
For Full prescribing information call 1 888 545 5973 **or visit** *www.elancolabels.com/us/zenrelia***.**

WARNING: VACCINE-INDUCED DISEASE AND INADEQUATE IMMUNE RESPONSE TO VACCINES. Based on results of the vaccine response study, dogs receiving Zenrelia are at risk of fatal vaccine-induced disease from modified live virus vaccines and inadequate immune response to any vaccine. Discontinue Zenrelia for at least 28 days to 3 months prior to vaccination and withhold Zenrelia for at least 28 days after vaccination. Dogs should be up to date on vaccinations prior to starting Zenrelia. Do not use in dogs less than 12 months old or dogs with a serious infection. Monitor dogs for infections because Zenrelia may increase susceptibility to opportunistic infections. Neoplastic conditions (benign and malignant) were observed during clinical studies. Consider the risks and benefits of treatment in dogs with a history of recurrence of these conditions. The most common adverse reactions were vomiting, diarrhea and lethargy. Zenrelia has not been evaluated in breeding, pregnant, or lactating dogs and concurrent use with glucocorticoids, cyclosporine, or other systemic immunosuppressive agents has not been tested. For full prescribing information see package insert.

[1]Forster S, Boegel A, Despa S, et al. Comparative efficacy and safety of ilunocitinib and oclacitinib for the control of pruritus and associated skin lesions in dogs with atopic dermatitis. Veterinary Dermatology. 2025; 1–10.

See pages 7 & 8 for product information summary.

Elanco™

Zenrelia ***is a treatment for canine allergic itch and inflammation that provides fast and effective relief with just once-daily dosing from the very start.***[1]

Zenrelia is indicated for control of pruritus associated with allergic dermatitis and control of atopic dermatitis in dogs at least 12 months of age.

Zenrelia helps dogs achieve clinical remission of itch (PVAS <2).[1]

Works fast[1]

Simple once-daily dosing

No loading or tapering, minimizing the opportunity for rebound of itch[1]

Continuous efficacy

Works over the long term, also significantly reducing lesions and inflammation[1]

Get dogs back to normal with Zenrelia

Visit ZenreliaForVets.com

infections, and its use has not been established in pregnant, breeding, or lactating dogs. In addition, Zenrelia should be discontinued for at least 28 days to 3 months prior to vaccination and withheld for at least 28 days after vaccination.

Conclusion

Zenrelia is a JAK inhibitor that has been proven to be safe and beneficial for many canine patients with allergic dermatitis. It can be used to manage multiple types of allergic dermatitis, including atopy, contact allergies, food allergies, and flea-allergic dermatitis. In addition, Zenrelia's convenient, once-daily administration from the start makes treatment straightforward for clients, helping to improve compliance.

Although treatment outcomes are inherently variable and influenced by numerous factors, the case studies presented[a] illustrate how Zenrelia can significantly impact the lives of dogs with allergic dermatitis and their owners. Because dogs can have varying clinical responses to different JAK inhibitors, having multiple options available allows veterinarians to address the needs of a broader range of canine patients suffering from allergic disease. ●

JAK = Janus kinase

[a]All cases discussed in this article are based on real case presentations and have been shared with permission from their respective owners.

References

1. Drechsler Y, Dong C, Clark DE, Kaur G. Canine atopic dermatitis: prevalence, impact, and management strategies. *Vet Med (Auckl)*. 2024;15:15-29. doi:10.2147/VMRR.S412570
2. Rybnícek J, Lau-Gillard PJ, Harvey R, Hill PB. Further validation of a pruritus severity scale for use in dogs. *Vet Dermatol*. 2009;20(2):115-122. doi:10.1111/j.1365-3164.2008.00728.x
3. Forster S, Trout CM, Despa S, Boegel A, Berger D, King S. Efficacy and field safety of ilunocitinib for the control of atopic dermatitis in client-owned dogs: a multicentre, double-masked, randomised, placebo-controlled clinical trial. *Vet Dermatol*. 2025;00:1-11. doi:10.1111/vde.13344
4. Talamonti Z, Cassis C, Brambilla PG, et al. Preliminary study of pet owner adherence in behaviour, cardiology, urology, and oncology fields. *Vet Med Int*. 2015;2015:618216. doi:10.1155/2015/618216
5. Olivry T, Lokianskiene V, Blanco A, Mestre PD, Bergvall K, Beco L. A randomised controlled trial testing the rebound-preventing benefit of four days of prednisolone during the induction of oclacitinib therapy in dogs with atopic dermatitis. *Vet Dermatol*. 2023;34(2):99-106. doi:10.1111/vde.13134
6. Kuntz EA, Gabor L, Toutain CE. Safety of ilunocitinib tablets (Zenrelia™) after once daily oral administration in dogs. *BMC Vet Res*. 2025;21(1):144. doi:10.1186/s12917-025-04579-1

Zenrelia™

(ilunocitinib tablets)

Immunomodulator
For oral use in dogs only

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

Before using Zenrelia, please consult the product insert, a summary of which follows:

WARNING: VACCINE-INDUCED DISEASE AND INADEQUATE IMMUNE RESPONSE TO VACCINES

Based on results of the vaccine response study, dogs receiving Zenrelia are at risk of fatal vaccine-induced disease from modified live virus vaccines and inadequate immune response to any vaccine. Discontinue Zenrelia for at least 28 days to 3 months prior to vaccination and withhold Zenrelia for at least 28 days after vaccination (see Warnings and Target Animal Safety).

INDICATIONS

Zenrelia is indicated for control of pruritus associated with allergic dermatitis and control of atopic dermatitis in dogs at least 12 months of age.

DOSAGE AND ADMINISTRATION

The dose of Zenrelia (ilunocitinib tablets) is 0.27 to 0.36 mg ilunocitinib/lb (0.6 to 0.8 mg ilunocitinib/kg) body weight, administered orally, once daily, with or without food.

Dosing Chart

Weight Range (in lb)	Weight Range (in kg)	Number of Tablets to be Administered			
		4.8 mg tablets	6.4 mg tablets	8.5 mg tablets	15 mg tablets
6.6 – 8.8	3.0 - 4.0	0.5			
8.9 – 11.8	4.1 – 5.3		0.5		
11.9 – 14.3	5.4 – 6.5			0.5	
14.4 – 17.7	6.6 – 8.0	1			
17.8 – 23.6	8.1 – 10.6		1		
23.7 – 31.1	10.7 – 14.1			1	
31.2 – 35.4	14.2 – 16.0		1.5		
35.5 – 43.1	16.1 – 19.5			1.5	
43.2 – 55.0	19.6 – 24.9				1
55.1 – 62.5	25.0 – 28.3			2	
62.6 – 83.3	28.4 – 37.4				1.5
83.4 – 110.0	37.5 – 49.9				2
110.1 – 137.5	50.0 – 62.4				2.5
137.6 – 166.0	62.5 – 74.9				3
≥ 166.1	≥ 75	Administer the appropriate combination of tablet strengths			

See product insert for complete dosing and administration information.

WARNINGS

User Safety Warnings

Not for use in humans. Keep this drug out of the reach of children. Wash hands immediately after handling tablets. In case of accidental ingestion, seek medical attention immediately.

Animal Safety Warnings

Due to the risk of fatal vaccine-induced disease from modified live virus vaccines and inadequate immune response to any vaccine, including rabies vaccines, do not administer vaccines to a dog receiving Zenrelia. Discontinue Zenrelia for at least 28 days to 3 months prior to vaccination and withhold Zenrelia for at least 28 days after vaccination (see **Target Animal Safety**).

Dogs should be monitored for the development of infections because Zenrelia may increase susceptibility to opportunistic infections, including demodicosis, interdigital furunculosis, coccidiosis, and pneumonia, and exacerbation of subclinical or uncomplicated infections (see **Target Animal Safety** and **Adverse Reactions**).

Zenrelia is not for use in dogs with serious infections.

Zenrelia may cause a progressive or persistently decreased hematocrit, hemoglobin, and/or red blood cell count without a corresponding increase in absolute reticulocyte count (see **Target Animal Safety**).

New neoplastic conditions (benign and malignant) were observed in dogs treated with Zenrelia during clinical studies (see **Adverse Reactions**).

Consider the risks and benefits of treatment prior to initiating Zenrelia in dogs with a history of recurrent serious infections or recurrent demodicosis or neoplasia (see **Adverse Reactions** and **Target Animal Safety**).

Zenrelia modulates the immune system.

Zenrelia is not for use in dogs less than 12 months of age (see **Target Animal Safety**).

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

PRECAUTIONS

Dogs should be up to date on vaccinations prior to starting Zenrelia (see **Target Animal Safety**).

The safe use of Zenrelia has not been evaluated in breeding, pregnant, or lactating dogs.

Decreased prostate gland weights in intact male dogs were observed in a laboratory safety study (see **Target Animal Safety**).

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

ADVERSE REACTIONS

Control of Atopic Dermatitis

In a masked field study assessing effectiveness and safety of Zenrelia for the control of atopic dermatitis in dogs, 181 Zenrelia-treated dogs and 87 placebo-treated dogs diagnosed with atopic dermatitis were evaluated for safety up to 112 days. By Day 112, 66.7% of placebo-treated dogs and 22.1% of Zenrelia-treated dogs exited the study. Adverse reactions seen during the field study are summarized in Table 1 below.

Table 1. Adverse Reactions through Day 112

Adverse Reaction	Zenrelia N = 181 Number of Dogs (%)	Placebo N = 87 Number of Dogs (%)
Vomiting or nausea	40 (22.1 %)	14 (16.1 %)
Diarrhea	36 (19.9 %)	9 (10.3 %)
Lethargy	22 (12.2 %)	9 (10.3 %)
Otitis externa	19 (10.5 %)	20 (23.0 %)
Anorexia	17 (9.4 %)	7 (8.0 %)
Dermal growth (e.g., cyst, papilloma)	16 (8.8 %)	4 (4.6 %)
Epiphora or ocular discharge	14 (7.7 %)	1 (1.1 %)
Coughing or wheezing, including respiratory infections	12 (6.6 %)	2 (2.3 %)
Bacterial skin infection	10 (5.5 %)	9 (10.3 %)
Elevated liver enzyme(s)	10 (5.5 %)	2 (2.3 %)
Urinary tract infection	10 (5.5 %)	2 (2.3 %)
Upset stomach, including flatulence and abdominal pain	10 (5.5 %)	0
Leukopenia	9 (4.9 %)	1 (1.1 %)
Sneezing	8 (4.4 %)	1 (1.1 %)
Lipoma	7 (3.9 %)	1 (1.1 %)
Weight gain	7 (3.9 %)	0
Increased water intake	4 (2.2 %)	2 (2.3 %)
Gingivitis (occurrence or worsening)	4 (2.2 %)	0
Blood in stool	4 (2.2 %)	0
Elevated total bilirubin	4 (2.2 %)	0
Elevated triglyceride	4 (2.2 %)	0
Histiocytoma	3 (1.7 %)	0
Increased appetite	3 (1.7 %)	0
Fungal skin infection	3 (1.7 %)	2 (2.3 %)
Weight loss	2 (1.1 %)	1 (1.1 %)
Metastatic neoplasia (i.e., hemangiosarcoma)	1 (0.6 %)	0
Systemic fungal infection	1 (0.6 %)	0
Mast cell tumor	1 (0.6 %)	0

N = number of dogs

Abnormal hematology results likely related to Zenrelia treatment included thrombocytopenia, leukopenia, neutropenia, lymphopenia, eosinopenia, monocytopenia, and decreased red blood cell count.

Abnormal serum chemistry results likely related to Zenrelia treatment included increased hepatobiliary parameters (alanine transaminase, aspartate aminotransferase, alkaline phosphatase, gamma-glutamyl transferase, and total bilirubin), increased blood urea nitrogen (concurrently with an increase in creatinine for one dog), hypertriglyceridemia, hypercholesterolemia, hypoalbuminemia (without a concurrent hyperglobulinemia), and hypoglobulinemia (with or without a decrease in total protein).

Twelve Zenrelia-treated dogs withdrew from the study early due to an adverse reaction, nine of which were considered likely related to Zenrelia treatment. These reactions included repeated episodes of vomiting, leukopenia, neutropenia, worsening of pre-existing lymphocytosis, enlargement of a non-resolving histiocytoma, eyelid mass with bacterial blepharitis, otitis interna with vestibular disease, urinary tract infection, and upper respiratory infection. Five placebo dogs withdrew from the study early due to an adverse reaction (i.e., lethargy, worsening of pre-existing lymphocytosis, occurrence of nystagmus, skin infection, and teat infection).

One Zenrelia-treated dog was diagnosed with splenic and liver masses on Day 112. Histopathologic diagnosis after euthanasia one month later confirmed metastatic splenic and hepatic hemangiosarcoma. Another Zenrelia-treated dog experienced traumatic tendonitis and a puncture wound four days prior to study completion, which progressed to a serious infection. The owner elected amputation after study completion. A third Zenrelia-treated dog experienced a moderate neutropenia on Day 28 associated with a pre-existing subclinical urinary tract infection (UTI) that had progressed into a clinical UTI. The neutrophil count normalized seven days later while still receiving Zenrelia, prior to exiting the study to receive antibiotics.

Control of Pruritus Associated with Allergic Dermatitis

In a masked field study assessing effectiveness and safety of Zenrelia for the control of pruritus associated with allergic dermatitis in dogs, 206 Zenrelia-treated dogs and 100 placebo-treated dogs diagnosed with allergic dermatitis were evaluated for safety up to 112 days. By Day 112, 84% of placebo-treated dogs and 49.5% of Zenrelia-treated dogs exited the study. Adverse reactions seen during the field study are summarized in Table 2 below.

Table 2. Adverse Reactions through Day 112

Adverse Reaction	Zenrelia N = 206 Number of Dogs (%)	Placebo N = 100 Number of Dogs (%)
Vomiting or nausea	32 (15.5%)	11 (11.0 %)
Diarrhea	26 (12.2 %)	5 (5.0 %)
Lethargy	25 (12.1 %)	7 (7.0 %)
Urinary tract infection	13 (6.3 %)	2 (2.0 %)
Anorexia	10 (4.9 %)	3 (3.0 %)
Coughing, wheezing, or difficulty breathing	9 (4.4 %)	0
Elevated liver enzyme(s)	8 (3.9 %)	0
Otitis externa	8 (3.9 %)	5 (5.0 %)
Increased water intake	7 (3.4 %)	2 (2.0 %)
Upset stomach, including flatulence, retching, and abdominal pain	5 (2.4 %)	4 (4.0 %)
Ocular discharge	5 (2.4 %)	1 (1.0 %)
Elevated triglyceride	5 (2.4 %)	0
Dermal or subcutaneous growth (e.g., cyst, nodule)	3 (1.5 %)	2 (2.0 %)
Sneezing	3 (1.5 %)	0
Blood in stool	3 (1.5 %)	0
Increased urination	3 (1.5 %)	0
Bacterial skin infection	2 (1.0 %)	4 (4.0 %)
Weight gain	2 (1.0 %)	0
Neurological disorder (e.g., tremors, ataxia)	2 (1.0 %)	0
Increased appetite	1 (0.5 %)	0
Fungal skin infection	1 (0.5 %)	0
Fever	1 (0.5 %)	0
Hematuria (without urinary tract infection)	1 (0.5 %)	0

N = number of dogs

Abnormal hematology results likely related to Zenrelia treatment included thrombocytosis, leukopenia, neutropenia, eosinopenia, and monocytopenia.

Abnormal serum chemistry results likely related to Zenrelia treatment included increased hepatobiliary parameters (alanine transaminase, aspartate aminotransferase, alkaline phosphatase, gamma-glutamyl transferase, and total bilirubin), increased blood urea nitrogen, increased creatinine, hypertriglyceridemia, hypercholesterolemia, hypoproteinemia, and hypoglobulinemia (with or without a decrease in total protein).

Seven Zenrelia-treated dogs withdrew from the study early due to an adverse reaction, four of which were considered likely related to Zenrelia treatment. These reactions included vomiting, lethargy, soft stool, neutropenia, increased liver enzymes, fever, abdominal discomfort, coughing, and wheezing. Four placebo treated dogs also withdrew from the study early due to an adverse reaction (i.e., splenic hemangiosarcoma, restlessness, abdominal pain, lethargy, and vomiting).

CONTACT INFORMATION

To report suspected adverse events, for technical assistance, or to obtain a copy of the Safety Data Sheet (SDS), contact Elanco US Inc at 1-888-545-5973.

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

EFFECTIVENESS

Control of Atopic Dermatitis:

A masked, placebo-controlled field study was conducted at 25 veterinary clinics in the US and Canada, enrolling 268 client-owned dogs diagnosed with atopic dermatitis and having at least moderate pruritus and mild skin lesions. Dogs were randomized to once daily treatment with Zenrelia at 0.6 – 0.8 mg/kg or placebo, at a ratio of 2:1 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) or a ≥ 50% reduction from baseline in veterinarian-assessed skin lesion scores on the Canine Atopic Dermatitis Extent and Severity Index version 4 (CADESI-4) on Day 28. The proportion of dogs in the Zenrelia group that were treatment successes was greater than and significantly different from the placebo group on Day 28 (Table 3, below).

Table 3. Estimated Proportion of Dogs Achieving Treatment Success

Treatment Group	Estimated Proportion of Success*
Zenrelia (N = 172)	0.83
Placebo (N = 77)	0.31†

* Based on back-transformed least squares means.
† Placebo vs. Zenrelia $p < 0.001$
N = Number of dogs

The Zenrelia group had a higher proportion of dogs with a ≥ 50% reduction from baseline in both owner-assessed PVAS and veterinarian-assessed CADESI-4 scores, compared to placebo, at all time points. The mean owner-assessed PVAS and veterinarian-assessed CADESI-4 scores were also lower for the Zenrelia group compared to the placebo group at all time points.

Control of Pruritus Associated with Allergic Dermatitis

A masked, placebo-controlled field study was conducted at 15 veterinary clinics in the US, enrolling 306 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: atopic dermatitis, contact dermatitis, flea allergy dermatitis, food hypersensitivity, or other. Dogs were randomized to once daily treatment with Zenrelia at 0.6 – 0.8 mg/kg or placebo, at a ratio of 2:1 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 Zenrelia group that were treatment successes was greater than and significantly different compared to the placebo group on Day 7 (Table 4, below).

Table 4. Estimated Proportion of Dogs Achieving Treatment Success

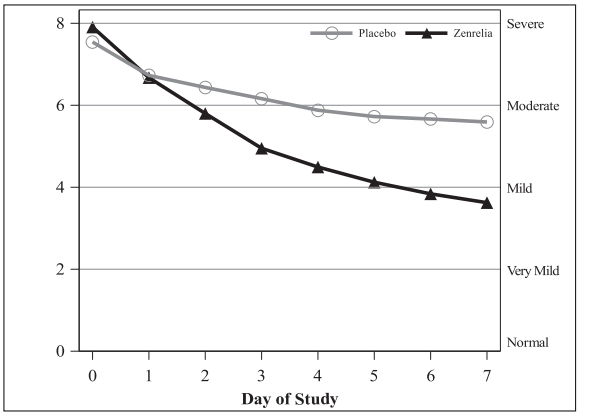
Treatment Group	Estimated Proportion of Success*
Zenrelia (N = 193)	0.25
Placebo (N = 91)	0.08†

* Based on back-transformed least squares means.
† Placebo vs. Zenrelia p = 0.006
N = number of dogs

The Zenrelia group had a higher proportion of dogs with a ≥ 50% reduction from baseline in owner-assessed PVAS, compared to placebo, on Days 2 through 7.

After Day 1, mean owner-assessed PVAS scores were lower in the Zenrelia group (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 Zenrelia group compared to the placebo group at all time points through Day 28.

STORAGE CONDITIONS

Store at room temperature between 15 to 25°C (59 to 77°F), excursions permitted between 5 to 40°C (41 to 104°F).

HOW SUPPLIED

Zenrelia (ilunocitinib tablets) is available in scored tablets in four strengths: 4.8 mg, 6.4 mg, 8.5 mg, and 15 mg. Each tablet strength is available in 10 and 30 count blister packages and 90 count bottles.

Manufactured for Elanco US Inc. Greenfield, IN 46140

Approved by FDA under NADA # 141-585

July 2024