

Peer-Reviewed Publication on the Efficacy and Field Safety of Zenrelia® (ilunocitinib tablets) for the Control of Atopic Dermatitis in Client Owned Dogs, is Available



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ORIGINAL ARTICLE

Veterinary Dermatology

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

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Abstract

Background: Inhibition of the Janus kinase (JAK) pathway is a well-established option for canine atopic dermatitis (cAD).

Objective: To evaluate the efficacy and safety of ilunocitinib, a novel JAK inhibitor for the control of pruritus and skin lesions in client-owned dogs with cAD.

Animals: Two hundred sixty-eight dogs at 25 veterinary clinics.

Materials and Methods: In this randomised, double-masked, clinical trial, dogs received either ilunocitinib ($n=181$, 0.6–0.8mg/kg) or placebo ($n=87$, 0.0mg/kg) tablets once daily for 112 days. Pruritus was assessed by owners using a pruritus Visual Analog Scale (PVAS), while skin lesions were assessed by Investigators using the cAD Extent and Severity Index, 4th iteration (CADESI-04). Treatment success was defined as $\geq 50\%$ reduction from baseline PVAS or CADESI-04 score on Day (D)28. Proportions of dogs achieving clinical remission from pruritus (PVAS<2) or skin lesions (CADESI-04<10) also were assessed.

Results: At D28, 83% of ilunocitinib-treated dogs achieved treatment success compared to 31% of placebo-treated dogs ($p<0.001$). A significantly higher proportion of ilunocitinib-treated dogs achieved $\geq 50\%$ reduction in CADESI-04 scores at all time points ($p<0.001$). The proportion of dogs achieving clinical remission PVAS or CADESI-04 scores was significantly higher in the ilunocitinib group starting on D7 and D14, respectively ($p<0.05$). The 112-day ilunocitinib treatment was well tolerated.

Conclusions and Clinical Relevance: Once daily ilunocitinib was well-tolerated and effective at rapidly reducing pruritus and resolving cAD-associated skin lesions. Clinical remission was achieved by two-thirds of dogs after 4 months of treatment. Ilunocitinib is safe and effective for managing clinical signs associated with cAD.

KEY WORDS

canine atopic dermatitis, clinical remission, ilunocitinib, JAK inhibitor, pruritus, skin lesions

INTRODUCTION

Canine atopic dermatitis (cAD) is a chronic inflammatory skin disease, with pruritus being the primary clinical sign. Skin lesions are either primary (erythema, erythematous macular or papular eruptions) or secondary to pruritic manifestations (excoriations, self-induced alopecia and lichenification).¹ Secondary

complications such as bacterial or fungal colonisation and infections are common.² The pathogenesis of cAD is complex and multifactorial involving genetic and environmental factors, as well as a defective skin barrier.³ Diagnosis is based on history, clinical features and exclusion of other pruritic skin diseases, including flea and/or food allergies in nonseasonal patterns.¹ It is therefore critical to control pruritus and

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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, including the Boxed Warning, before using this drug. For full prescribing information call 1 888 545 5973 or visit www.elancolabels.com/us/zenrelia.

WARNING: INADEQUATE IMMUNE RESPONSE TO VACCINES. Based on results of the vaccine response study, dogs receiving Zenrelia are at risk of an inadequate immune response to vaccines. 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 infections, including adenoviral hepatitis and pancreatitis. 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.

Zenrelia™
(ilunocitinib tablets)