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Kuntz *et al. BMC Veterinary Research* (2025) 21:144
https://doi.org/10.1186/s12917-025-04579-1

BMC Veterinary Research

RESEARCH Open Access

Safety of ilunocitinib tablets (Zenrelia™) after once daily oral administration in dogs

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Abstract

Background Ilunocitinib is a new molecular entity of the Janus kinase inhibitor (JAKi) class for the treatment and control of symptoms of allergic skin disease conditions, such as pruritus and skin lesions in dogs. This laboratory study with ilunocitinib tablets (Zenrelia™, Elanco) investigated the safety in healthy dogs treated once daily for 6 months. The study was a randomized, blinded, parallel-group design examining one (1X), two (2X), three (3X) and five (5X) times the maximum recommended dose (0.8 mg/kg) compared to sham dosed control dogs.

Methods Twenty male and 20 female healthy Beagle dogs, 11 to 12-month of age, with a mean body weight ranging from 9.85 to 10.46 kg, were randomized to an untreated control group or ilunocitinib treatment groups at daily dose rates of 0.8 mg/kg (1X), 1.6 mg/kg (2X), 2.4 mg/kg (3X), or 4.0 mg/kg (5X) over six months. All animals were fed within 30 min prior to treatment. Safety assessments included general health observations, clinical observations (including complete physical and neurological examinations), ophthalmology, clinical pathology, peripheral blood immunophenotyping, body weight, food consumption, pharmacokinetic blood collections, organ macroscopic and microscopic examinations.

Results No effects of the treatment were noted on body weight, food consumption, physical and neurological examinations, urinalysis, peripheral blood immunophenotype, and ophthalmoscopic examinations. Clinical findings included non-exudative skin lesions, skin lesions with discharge, swollen paw(s), skin thickening, skin discoloration or scabbing of the feet (paws/digits), in both male and female dogs. Changes in clinical pathology included marginally decreased red cell mass, lower eosinophils, higher C-reactive protein, total protein and fibrinogen, lower albumin and albumin: globulin levels. Microscopic findings included skin inflammation and focal dermatitis/furunculosis.

Conclusions Ilunocitinib was well tolerated when administered daily over six months at 0.8 mg/kg and multiples thereof up to 4.0 mg/kg in Beagle dogs. At the therapeutic dose, no clinically significant changes were observed. Minimal changes in hematological parameters, total protein, and fibrinogen were noted at the higher doses. All of these findings, consistent with the known pharmacology of the JAKi class at exaggerated dosing, support the safe and chronic use of Zenrelia™ tablets.

Clinical trial number Not applicable.

Keywords Ilunocitinib, Zenrelia™, Safety, Dog, Oral

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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 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.

Zenrelia™
(ilunocitinib tablets)