WHEN TO REACH FOR APOQUEL® OR CYTOPoint®

**FIRST CHOICE FOR FAST RELIEF**
- Rapid relief of allergic itch within 24 hours\(^1,2\)
- Short- and long-term management of allergic itch
- Management of flares of allergic dermatitis
- Significant reduction of inflammation due to allergic dermatitis\(^1,3\)
- Start-and-stop itch control
- Does not interfere with allergy testing\(^4\)
- For dogs at least 12 months of age

- For dogs starting food elimination diets
- For dogs allergic to pork

Provide individualized treatment of allergic and atopic dermatitis with trusted treatment options

**CYTOPoint**

ONE INJECTION. LASTING RELIEF.
- Begins to relieve allergic pruritus within 24 hours and lasts for 4 to 8 weeks\(^5\)
- Lifelong treatment of allergic and atopic dermatitis
- Treatment of flakes of allergic dermatitis
- For owners seeking nondrug therapy
- For dogs who are difficult to pill or cases in which owner compliance is a concern
- For dogs with comorbidities
- Safe for dogs of all ages

\(^1\) Data on file.\(^2\) Total of 218 dogs.\(^3\) Likelihood of flare: 1 - unlikely, 2 - possible, 3 - likely.\(^4\) In a study of 22 dogs with atopic dermatitis.\(^5\) Data on file.
Reach for relief based on your patient’s needs:

**RORY**
- 2 years old
- First-time itch patient
- Licks his paws and rubs his face due to allergic itch with secondary skin inflammation
- **Reach for Apoquel Chewable for rapid allergic itch relief within 24 hours**\(^1\,^2\)
- Apoquel Chewable can make daily dosing easier, supporting medication compliance and delivering on pet owner preferences

**SKYLAR**
- 3 years old
- Enjoys playing outside, running and rolling around in the grass
- Suffers from atopic dermatitis and severe, seasonal pruritic flares
- **Reach for either Apoquel Chewable or Cytopoint for pruritic flares during allergy season**

**NALA**
- 5 years old
- Tags along on road trips
- Owner has difficulty pilling
- **Reach for either Apoquel Chewable or Cytopoint to achieve lasting allergic pruritus relief for dogs who have owners with on-the-go lifestyles**

The examples above represent hypothetical patient scenarios.

**Cytopoint Indications:** Cytopoint has been shown to be effective for the treatment of dogs against allergic dermatitis and atopic dermatitis.

**Apoquel and Apoquel Chewable Indications:** Control of pruritus associated with allergic dermatitis and control of atopic dermatitis in dogs at least 12 months of age.

**Apoquel and Apoquel Chewable Important Safety Information:** Do not use Apoquel or Apoquel Chewable in dogs less than 12 months of age or those with serious infections. Apoquel and Apoquel Chewable may increase the chances of developing serious infections, and may cause existing parasitic skin infestations or pre-existing cancers to get worse. Consider the risks and benefits of treatment in dogs with a history of recurrence of these conditions. New neoplastic conditions (benign and malignant) were observed in clinical studies and post-approval. Apoquel and Apoquel Chewable have not been tested in dogs receiving some medications including some commonly used to treat skin conditions such as corticosteroids and cyclosporines. Do not use in breeding, pregnant, or lactating dogs. Most common side effects are vomiting and diarrhea. Apoquel and Apoquel Chewable have been used safely with many common medications including parasiticides, antibiotics and vaccines.

**See accompanying full Prescribing Information.**

In a masked field study to assess the effectiveness and safety of oclacitinib for the control of atopic dermatitis in dogs, 152 dogs treated with APOQUEL and 147 dogs treated with placebo (vehicle control) were evaluated for safety. The majority of dogs in the placebo group withdrew from the 112-day study by Day 16. Adverse reactions reported (and percent of dogs affected) during Days 0-16 included diarrhea (4.6% APOQUEL, 3.4% placebo), vomiting (3.9% APOQUEL, 4.1% placebo), anorexia (2.6% APOQUEL, 0% placebo), new cutaneous or subcutaneous lump (2.6% APOQUEL, 2.7% placebo), and lethargy (0.2% APOQUEL, 1.4% placebo). In most cases, diarrhea, vomiting, anorexia, and lethargy spontaneously resolved with continued dosing. Dogs on APOQUEL had decreased leukocytes (neutrophil, eosinophil, and monocyte counts) and serum globulin, and increased cholesterol and lipase compared to the placebo group but group means remained within the normal range. Mean lymphocyte counts were transiently increased at Day 14 in the APOQUEL group.

Dogs that withdrew from the masked field study could enter an unmasked study where all dogs received APOQUEL. Between the masked and unmasked study, 283 dogs received at least one dose of APOQUEL. Of these 283 dogs, two were withdrawn from study due to suspected treatment-related adverse reactions: one dog that had an intense flare of dermatitis and severe pyodermic pustules, and one dog that developed generalized demodicosis after 28 days of APOQUEL administration. Two other dogs on APOQUEL were withdrawn from study due to suspected or confirmed malignant neoplasia and subsequently euthanized, including one dog that developed signs associated with a heart base mass after 21 days of APOQUEL administration, and one dog that developed a Grade III mast cell tumor after 60 days of APOQUEL administration.

One of the 147 dogs in the placebo group developed a Grade I mast cell tumor and was withdrawn from the masked study. Additional dogs receiving APOQUEL were hospitalized for diagnosis and treatment of pneumonia (one dog), transient bloody vomiting and stool (one dog), and cystitis with urethralis (one dog). In the 283 dogs that received APOQUEL, the following additional clinical signs were reported after beginning APOQUEL (percentage of dogs with at least one report of the clinical sign as a non-pre-existing finding): pyodermia (12.0%), non-specific dermal lumps (12.0%), otitis (9.9%), vomiting (9.2%), diarrhea (6.0%), histiocytoma (3.9%), cystitis (3.5%), anorexia (3.2%), lethargy (2.8%), yeast skin infections (2.5%), pododermatitis (2.5%), lipoma (2.1%), polydipsia (1.4%), lymphadenopathy (1.1%), nausea (1.1%), increased appetite (1.1%), aggression (1.1%), and weight loss (0.7).
Clinical Pharmacology:

Mechanism of Action

Oclacitinib inhibits the function of a variety of pruritogenic cytokines and pro-inflammatory cytokines, as well as cytokines involved in allergy that are dependent on JAK1 or JAK3 enzyme activity. It has little effect on cytokines involved in hemopoiesis that are dependent on JAK2. Oclacitinib is not a corticosteroid or an antihistamine.

Pharmacokinetics

In dogs, oclacitinib maleate is rapidly and well absorbed following oral administration, with mean time to peak plasma concentrations (T_max) of less than 1 hour. Following oral administration of 0.4-0.6 mg oclacitinib/kg to 24 dogs, the mean (90% confidence limits [CL]) maximum concentration (C_{max}) was 204 (38.1, 372) ng/mL and the mean area under the plasma concentration-time curve from 0 and extrapolated to infinity (AUC_{0-inf}) was 1890 (1690, 2110) ng·hr/mL. The prandial state of dogs does not significantly affect the rate or extent of absorption. The absolute bioavailability of oclacitinib maleate was 89%.

Oclacitinib has low protein binding with 66.3-69.7% bound in fortificant canine plasma at nominal concentrations ranging from 10-1000 ng/mL. The apparent mean (95% CL) volume of distribution at steady-state was 942 (870, 1014) mL/kg body weight.

Oclacitinib is metabolized in the dog to multiple metabolites and one major oxidative metabolite was identified in plasma and urine. Overall the major clearance route is metabolism with minor contributions from renal and biliary elimination. Inhibition of canine cytochrome P450 enzymes by oclacitinib is minimal; the inhibitory concentrations (IC_{50}) are 50 fold greater than the observed C_{max} values at the use dose.

Mean (95% CL) total body oclacitinib clearance from plasma was low – 316 (237, 396) ml/kg body weight (5.3 mL/min/kg body weight). Following IV and PO administration, the terminal T_1/2 appeared similar with mean values of 3.5 (2.2, 4.7) and 4.1 (3.1, 5.2) hours, respectively.

Effectiveness:

Control of Atopic Dermatitis

A double-masked, 112-day, controlled study was conducted at 18 U.S. veterinary hospitals. The study enrolled 299 client-owned dogs with atopic dermatitis. Dogs were randomized to treatment with oclacitinib maleate (APOQUEL®) (152 dogs: tablets administered at a dose of 0.4-0.6 mg/kg, once daily for 14 days and then once daily) or placebo (147 dogs: vehicle control, tablets administered on the same schedule). The study was unblinded to the Owner after Day 28. Treatment success for skin lesions was defined as a 50% decrease from the baseline Canine Atopic Dermatitis Extent and Severity Index (CADESI) score, assessed by the Veterinarian, on Day 28. The estimated proportion of dogs with Treatment Success in Owner-assessed pruritus VAS score and in Veterinarian-assessed CADESI score was greater and significantly different for the APOQUEL group compared to the placebo group.

Estimated Proportion of Dogs with Treatment Success, Atopic Dermatitis

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Compared to the placebo group, mean Owner-assessed pruritus VAS scores (on Days 1, 2, 7, 14, and 28) and Veterinarian-assessed CADESI scores (on Days 14 and 28) were lower (improved) in dogs in the APOQUEL group. By Day 30, 86% (127/147) of the placebo group dogs and 15% (23/152) of the APOQUEL group dogs withdrew from the masked study because of worsening clinical signs, and had the option to enrol in an unmasked study and receive APOQUEL. For dogs that continued APOQUEL treatment beyond one month, the mean Owner-assessed pruritus VAS scores and Veterinarian-assessed CADESI scores continued to improve through study end at Day 112.

Control of Pruritus Associated with Allergic Dermatitis

A double-masked, 30-day, controlled study was conducted at 26 U.S. veterinary hospitals. The study enrolled 436 client-owned dogs with a history of allergic dermatitis attributed to one or more of the following conditions: atopic dermatitis, flea allergy, food allergy, contact allergy, and other/unspecified allergic dermatitis. Dogs were randomized to treatment with APOQUEL (216 dogs: tablets administered at a dose of 0.4-0.6 mg/kg twice daily) or placebo (220 dogs: vehicle control, tablets administered twice daily). During the study, dogs could not be treated with other drugs that could affect the assessment of effectiveness, such as corticosteroids, anti-histamines, or cyclosporine. Treatment success for pruritus in each dog was defined as at least a 2 cm decrease from baseline on a 10 cm visual analog scale (VAS) in pruritus.

Compared to the placebo group, mean Owner-assessed pruritus VAS scores (on Days 1, 2, 14, and 28) and placebos were lower (improved) in dogs in the APOQUEL group. By Day 30, 86% (127/147) of the placebo group dogs and 15% (23/152) of the APOQUEL group dogs withdrew from the masked study because of worsening clinical signs, and had the option to enrol in an unmasked study and receive APOQUEL. For dogs that continued APOQUEL treatment beyond one month, the mean Owner-assessed pruritus VAS scores and Veterinarian-assessed CADESI scores continued to improve through study end at Day 112.

Effectiveness of Dogs with Treatment Success, Allergic Dermatitis

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Dosing Chart

The dose of APOQUEL CHEWABLE (oclacitinib chewable tablet) is 0.18 to 0.27 mg oclacitinib/lb (0.4 to 0.6 mg oclacitinib/kg) body weight, administered orally, to dogs at least 12 months of age.

Adverse Reactions, Post-Approval Experience

In a masked field study to assess the effectiveness and safety of oclacitinib for the control of atopic dermatitis in dogs, 205 dogs were treated with oclacitinib FCT and 199 dogs treated with placebo (vehicle control) were evaluated for safety. The majority of dogs in the placebo group withdrew from the 112-day study by Day 16. Adverse reactions reported (and percent of dogs affected) during Days 0-16 included diarrhea (4.6% oclacitinib FCT, 3.4% placebo), vomiting (3.9% oclacitinib FCT, 4.1% placebo), anorexia (2.6% oclacitinib FCT, 3.4% placebo), new cutaneous lesion (2.6% oclacitinib FCT, 2.7% placebo), and lethargy (2.0% oclacitinib FCT, 1.4% placebo). In most cases, diarrhea, vomiting, anorexia, and lethargy spontaneously resolved with continued dosing. Dogs on oclacitinib FCT had decreased leukocytes (neutrophil, eosinophil, and monocye counts) and increased cholesterol and lipase compared to the placebo group but group means remained within the normal range. Mean lymphocyte counts were transiently increased at Day 14 in the oclacitinib FCT group.

Dogs that withdrew from the masked field study could enter an unmasked study where all dogs received oclacitinib FCT. Between the masked and unmasked study, 283 dogs received at least one dose of oclacitinib FCT. Of these 283 dogs, two dogs were withdrawn from study due to suspected treatment-related adverse reactions: one dog that had an intense flare of dermatitis and severe secondary pyoderma after 19 days of oclacitinib FCT administration, and one dog that developed generalized demodicosis after 28 days of oclacitinib FCT administration. Two other dogs on oclacitinib FCT were withdrawn from study due to suspected or confirmed malignant neoplasia and subsequently euthanized, including one dog that developed signs suggestive of a heart base mass associated with a grade III mast cell tumor after 60 days of oclacitinib FCT administration.

The following adverse events reported (and percent of dogs affected) during Days 0-7 included diarrhea (2.3% oclacitinib FCT, 0.9% placebo), vomiting (2.3% oclacitinib FCT, 1.8% placebo), lethargy (1.8% oclacitinib FCT, 1.4% placebo), anorexia (1.8% oclacitinib FCT, 0.9% placebo), and polydipsia (1.4% oclacitinib FCT, 0% placebo). In most cases, signs spontaneously resolved with continued dosing. Five oclacitinib FCT group dogs were withdrawn from study because of: darkening areas of skin and fur (1 dog); diarrhea (1 dog); fever, lethargy and cystitis (1 dog); an inflamed footpad and vomiting (1 dog); and diarrhea, vomiting, and lethargy (1 dog). Dogs in the oclacitinib FCT group had a slight decrease in mean white blood cell counts (neutrophil, eosinophil, and monocyte counts) that remained within the normal reference range. Mean lymphocyte count for dogs in the oclacitinib FCT group increased at Day 7, but returned to pretreatment levels by study end without a break in oclacitinib FCT administration. Serum cholesterol increased in 25% of oclacitinib FCT group dogs, but mean cholesterol remained within the reference range.

Continuation Field Study

After completing oclacitinib FCT field studies, 239 dogs enrolled in an unmatched (no placebo control), continuation therapy study receiving oclacitinib FCT for an unrestricted period of time on one oclacitinib FCT administration. Six dogs were euthanized because of suspected malignant neoplasms: including thoracic metastatic, abdominal metastatic, splenic, frontal sinus, and intracranial neoplasms, and transitional cell carcinoma after 17, 120, 175, 49, 141, and 286 days of oclacitinib FCT administration, respectively. Two dogs each developed a Grade II mast cell tumor after 52 and 91 days of oclacitinib FCT administration, respectively. One dog developed low grade B-cell lymphoma after 392 days of oclacitinib FCT administration. Two dogs each developed an apocrine gland adenocarcinoma (one dorsal, one anal sac) after approximately 210 and 320 days of oclacitinib FCT administration, respectively. Two dogs each developed a low grade oral spindle cell sarcoma after 320 days of oclacitinib FCT administration.

Post-Approval Experience (2020)

The following adverse events are based on post-approval adverse drug experience reporting for oclacitinib FCT. Not all adverse events are reported to FDA/CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data. The following adverse events reported in dogs are listed in decreasing order of reporting frequency.

Vomiting, lethargy, anorexia, diarrhea, elevated liver enzymes, dermatitis (i.e. crusts, pemphigus, pemphigoid, pyoderma), and pruritus were reported.

Benign, malignant, and unclassified neoplasms, dermal masses (including papillomas and hemangiomas), lymphoma and other cancers have been reported.

Death (including euthanasia) has been reported.

Contact Information:

To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data Sheet, contact Zoetis Inc. at 1-888-963-8471 or www.zoetis.com.

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

Clinical Pharmacology:

Mechanism of Action

Oclacitinib inhibits the function of a variety of pruritogenic cytokines and pro-inflammatory cytokines, as well as cytokines involved in allergy that are dependent on JAK1 or JAK3 enzyme activity. It has little effect on cytokines involved in hematopoiesis that are dependent on JAK2. Oclacitinib is not a corticosteroid or an antihistamine.
In dogs, oclacitinib is rapidly and well absorbed following oral administration, with mean time to peak plasma concentrations (t_{max}) of less than 2 hours. Following oral administration of a single 5.4 mg APOQUEL CHEWABLE to 42 dogs, the mean C_{max} was 292 ng/mL and the mean area under the plasma concentration-time curve from 0 and extrapolated to infinity (AUC_{0-inf}) was 2570 ng·h/mL.

Oclacitinib has low protein binding with 66.3-69.7% bound in fortified canine plasma at nominal concentrations ranging from 10-1000 ng/mL. The apparent volume of distribution at steady-state was 942 (870, 1014) mL/kg body weight.

Mean (95% CI) total body oclacitinib clearance from plasma was low – 316 (237, 396) mL/h/kg body weight. Following intravenous and oral administration, the terminal half-life appeared similar with mean values of 3.5 (2.4, 4.7) and 4.1 (3.1, 5.2) hours, respectively.

Oclacitinib is metabolized in the dog to multiple metabolites and one major oxidative metabolite was identified in plasma and urine. Overall the major clearance route is metabolism with minor contributions from renal and biliary elimination. Inhibition of canine cytochrome P450 enzymes by oclacitinib, cytochromes (CYPs) CYP3A4, CYP2C19, and CYP3A24 were approximately 50 fold higher than the observed C_{max} values at the use dose.

Effectiveness:

The effectiveness of APOQUEL CHEWABLE was established by pharmacokinetic data comparing oclacitinib FCT to APOQUEL CHEWABLE (see Clinical Pharmacology). Bioequivalence was not met for the lower 90% CI of the maximum concentration (C_{max}), which may delay the speed of onset of effectiveness of APOQUEL CHEWABLE at the first dose or when transitioning from the oclacitinib FCT.

Control of Atopic Dermatitis

A double-masked, 112-day, controlled study was conducted at 18 U.S. veterinary hospitals. The study enrolled 299 client-owned dogs with atopic dermatitis. Dogs were randomized to treatment with oclacitinib FCT (152 dogs: tablets administered at a dose of 0.4-6.6 mg/kg per dose twice daily for 14 days and then once daily) or placebo (147 dogs: vehicle control, tablets administered on the same schedule). During the study, dogs could not be treated with other drugs that could affect the assessment of effectiveness, such as corticosteroids, anti-histamines, or cyclosporine. Treatment success for pruritus for each dog was defined as at least a 2 cm decrease from baseline on a 10 cm visual analog scale (VAS) in pruritus, assessed by the Owner, on Day 28. Treatment success for skin lesions was defined as a 50% decrease from baseline Canine Atopic Dermatitis Extent and Severity Index (CADESI) score, assessed by the Veterinarian, on Day 28. The estimated proportion of dogs with Treatment Success in Owner-assessed pruritus VAS score and in Veterinarian-assessed CADESI score was greater and significantly different for the oclacitinib FCT group compared to the placebo group.

Estimated Proportion of Dogs with Treatment Success, Atopic Dermatitis

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Compared to the placebo group, mean Owner-assessed pruritus VAS scores (on Days 1, 2, 7, 14, and 28) and Veterinarian-assessed CADESI scores (on Days 14 and 28) were lower (improved) in dogs in the oclacitinib FCT group. By Day 35, 86% (127/148) of the placebo group dogs and 15% (23/152) of the oclacitinib FCT group dogs withdrew from the masked study because of worsening clinical signs, and had the option to enroll in an unmasked study and receive oclacitinib FCT. For control of pruritus associated with Atopic Dermatitis, the estimated proportion of dogs with Treatment Success was greater and significantly different for the oclacitinib FCT group compared to the placebo group.

Control of Pruritus Associated with Allergic Dermatitis

A double-masked, 30-day, controlled study was conducted at 26 U.S. veterinary hospitals. The study enrolled 436 client-owned dogs with a history of allergic dermatitis attributed to one or more of the following conditions: atopic dermatitis, flea allergy, food allergy, contact allergy, and other/unspecified allergic dermatitis. Dogs were randomized to treatment with oclacitinib FCT (216 dogs: tablets administered at a dose of 0.4-6.6 mg/kg per dose twice daily or placebo (220 dogs: vehicle control, tablets administered twice daily). During the study, dogs could not be treated with other drugs that could affect the assessment of pruritus or dermal inflammation such as corticosteroids, anti-histamines, or cyclosporine. Treatment success for each dog was defined as at least a 2 cm decrease from baseline on a 10 cm visual analog scale (VAS) in pruritus, assessed by the Owner, on at least 5 of the 7 evaluation days. The estimated proportion of dogs with Treatment Success was greater and significantly different for the oclacitinib FCT group compared to the placebo group.

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After one week of treatment, 86.4% of oclacitinib FCT group dogs compared with 42.5% of placebo group dogs had achieved a 2 cm reduction on the 10 cm Owner-assessed pruritus VAS. On each of the 7 days, mean Owner-assessed pruritus VAS scores were lower in dogs in the oclacitinib FCT group (see Figure 1). Veterinarians used a 10 cm VAS scale to assess each dog’s dermatitis. After one week of treatment, the mean Veterinarian-assessed VAS dermatitis score for the dogs in the oclacitinib FCT group was lower at 2.2 cm (improved from a baseline value of 6.2 cm) compared with the placebo group mean score of 4.9 cm (from a baseline value of 6.2 cm). For dogs that continued oclacitinib FCT treatment beyond one week, the Veterinarian-assessed dermatitis scores continued to improve through study end at Day 30.

Figure 1: Owner Assessed Pruritus VAS Scores by treatment for Days 0-7

Painability

In a well-controlled U.S. field study, in which 1,662 dogs administered to 120 dogs, a total of 1,522 dogs (91.6%) were accepted voluntarily within 5 min. Of the 140 doses uncorrected after 5 min, 134 (9%) were consumed with assistance (with food treats or by pilling), and 6 (0.4%) doses were refused.

Animal Safety

Margin of Safety in 12 Month Old Dogs

Oclacitinib maleate was administered to healthy, one-year-old Beagle dogs twice daily for 1 week, followed by once daily for 20 weeks, at 0.6 mg/kg (1X maximum exposure dose, 8 dogs), 1.8 mg/kg (3X, 8 dogs), and 3.0 mg/kg (5X, 8 dogs) oclacitinib for 26 weeks. Eight dogs received placebo (empty gelatin capsule) at the same dosage schedule. Clinical observations that were considered likely to be related to oclacitinib maleate included polyuria, polydipsia, and a dose-dependent increase in the number of urinary red blood cell (RBC) in the urine. Additionally, pruritus interdigital furunculosis (cysts) on one or more feet during the study. During the additional clinical observations were primarily related to the interdigital furunculosis and included dermatitis (local alopecia, erythema, abrasions, scabbing/crusts, and edema of feet) and lymphadenopathy of peripheral nodes. Microscopic findings considered to be oclacitinib maleate-related included decreased cellularity (lymphoid) in Gut-Associated Lymphoid Tissue (GALT), spleen, thymus, cervical and mesenteric lymph nodes; and decreased cellularity of sternal and femoral bone marrow. Lymphoid hyperplasia and chronic active inflammation was seen in lymph nodes draining feet affected with interdigital furunculosis. Five oclacitinib maleate-treated dogs had microscopic evidence of mild interstitial pneumonia. Clinical pathology findings considered to be oclacitinib maleate-related included mild, dose-dependent reduction in hemoglobin, hematocrit, and reticulocyte counts during the twice daily dosing period with decreases in the leukocyte subsets of lymphocytes, eosinophils, and basophilis. Total proteins were decreased over time primarily due to the albumin fraction.

Vaccine Response Study

An adequate immune response (serology) to killed rabies (RVI), modified live canine distemper virus (CDV), and modified live canine parvovirus (CPV) vaccination was achieved in eight 16-week old vaccine naive puppies that were administered oclacitinib maleate at 1.8 mg/kg oclacitinib (3X maximum exposure dose) twice daily for 84 days. For modified live canine parainfluenza virus (PI), 80% (6/8) of the dogs achieved adequate serologic response. Clinical observations that were considered likely to be related to oclacitinib maleate treatment included enlarged lymph nodes, interdigital furunculosis, cysts, and pododermatitis. One oclacitinib maleate-treated dog (26-weeks-old) was euthanized on Day 74 after physical examination revealed the dog to be febrile, lethargic, with pale mucous membranes and frank blood in stool. Necropsy revealed pneumonia of short duration and evidence of chronic lymphadenitis of mesenteric lymph nodes. During the three month recovery phase to this study, one oclacitinib maleate-treated dog (32-weeks old) was euthanized on Day 28 due to clinical signs which included enlarged prescapular lymph nodes, interdigital furunculosis, cysts, and pododermatitis. One oclacitinib maleate-treated dog (26-weeks-old) was euthanized on Day 74 after physical examination revealed the dog to be febrile, lethargic, with pale mucous membranes and frank blood in stool. Necropsy revealed pneumonia of short duration and evidence of chronic lymphadenitis of mesenteric lymph nodes. During the three month recovery phase to this study, one oclacitinib maleate-treated dog (32-weeks old) was euthanized on Day 28 due to clinical signs which included enlarged prescapular lymph nodes, interdigital furunculosis, cysts, and pododermatitis.