






# Oclacitinib Maleate

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**Oclacitinib maleate is an oral, selective Janus kinase (JAK)-1 and JAK-3 inhibitor approved for treatment of hypersensitivity-induced cutaneous pruritus in dogs 12 months of age or older.**

## Clinical Applications

-  **Oclacitinib inhibits activity of pruritogenic, proinflammatory cytokines (eg, interleukin-2 [IL-2], IL-4, IL-6, IL-13, IL-31) via JAK-1 and JAK-3 inhibition.**
  - IL-31 is a mediator of canine pruritus.
-  **Oclacitinib offers rapid pruritus control of canine hypersensitivity syndromes without the adverse effects associated with glucocorticoids.**
  - Published clinical trials<sup>1,2</sup> demonstrated a statistically significant reduction in owner-observed pruritus within 24 hours.
    - By day 7 of therapy, ≥50% reduction in owner-assessed pruritus score was achieved in 70.5% of patients.<sup>1</sup>
    - As compared with prednisolone at 0.5 to 1.0 mg/kg PO once a day, oclacitinib at 0.4 to 0.6 mg/kg PO twice a day (label dose) achieved statistically equivalent pruritus reduction within 4 hours and maintained equivalent pruritus control during the 28-day study period.<sup>2</sup>
-  **Oclacitinib may significantly reduce pruritus in dogs with any form of cutaneous hypersensitivity, including atopic dermatitis, cutaneous adverse food reaction (CAFR), contact hypersensitivity, and hypersensitivity to *Sarcoptes scabiei* infestation.**
  - Care should be taken to identify and appropriately manage the primary cause of pruritus, as well as secondary bacterial and yeast infections.
    - Strict flea control measures and elimination diet trials should be used to rule out fleabite hypersensitivity and CAFR, respectively.
    - Patients with severe pruritus of the hock, elbow, ventrum, or pinna should be treated empirically for sarcoptic mange, even with negative results on skin scrape cytology (see **Canine Cutaneous Pruritus: Skin Scrape**, page 6).
  - To reach a diagnosis in patients with a cutaneous hypersensitivity, oclacitinib may be administered for initial pruritus control, with subsequent discontinuation of the drug.

CAFR = cutaneous adverse food reaction, IL = interleukin, JAK = Janus kinase

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## Canine Cutaneous Pruritus: Skin Scrape

### Perform a *superficial skin scrape* when

- Infestation of *Cheyletiella* spp is suspected (eg, scaling, pruritic dermatitis of the dorsum).
- *Sarcoptes scabiei* infestation is suspected (eg, severe pruritus of the hock, elbow, ventrum, pinna).
  - Of note, at least 50% of patients with sarcoptic mange will have a negative superficial skin scrape.<sup>9</sup>

### Perform a *deep skin scrape* when

- The patient has erythema, papules, pustules, crusts, alopecia, or comedones.

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### Anecdotaly, intradermal testing of dogs receiving oclacitinib has produced positive results after 1 month of use.

- Whether use of oclacitinib or another immunomodulator improves or reduces efficacy of immunotherapy is unknown.
- The impact of long-term use of oclacitinib on intradermal testing or serology assessment of allergen-specific IgE is unknown.
- Before referral for intradermal testing, clinicians should contact their veterinary dermatologist for medication withdrawal preferences.



### Previous response, or lack thereof, to other immunomodulating drugs (eg, glucocorticoids, cyclosporine) is not predictive of response to oclacitinib.



### Oclacitinib is not approved for use in cats.

- In one case involving feline cutaneous mastocytic dermatitis, the patient was successfully treated with 31 days of oclacitinib therapy at 1 mg/kg PO twice a day.<sup>3</sup>
- A recently published abstract described success of oclacitinib to control nonflea- and nonfood-induced hypersensitivity in 12 cats that received 0.4 to 0.6 mg/kg PO twice a day for 14 days, then once a day for 14 days.<sup>4</sup>
  - Owner-assessed efficacy was reported to be good or excellent in 4 cases.<sup>4</sup>

## Protocol & Side Effects



### The label dosage is 0.4 to 0.6 mg/kg PO twice a day for up to 14 days, then 0.4 to 0.6 mg/kg PO once a day indefinitely.<sup>5</sup>

- Once-a-day administration for long-term therapy allows for function of proinflammatory cytokines (eg, ILs), which are important for a healthy T-cell immune response, within the 24-hour period.
  - Oclacitinib may be discontinued without tapering.
- Pruritus may mildly increase with transition from twice-a-day therapy to once-a-day therapy.
  - Similarly, a missed dose in a patient maintained on once-a-day therapy may lead to rapid pruritus rebound.



### Reported side effects are few and include vomiting (2.3%, 5/216) and diarrhea (2.3%, 5/216), which are typically mild and self-limiting.<sup>1</sup>



**Because oclacitinib is an immunomodulating drug, patients may be more susceptible to infection, demodicosis, and neoplasia.<sup>5</sup>**

- The author has observed development of solitary oral papillomas in several dogs during oclacitinib therapy.

## Safety & Precautionary Measures



**Because oclacitinib is a new drug, the safety of long-term therapy is unknown.**

- In a study of 247 client-owned dogs treated with oclacitinib for up to 630 days, owners noted improved quality of life in >91% of the dogs.<sup>6</sup>
  - Hematology and serum biochemistry parameters were in the normal reference range.<sup>6</sup>
- In the author's experience, oclacitinib may be used continuously or intermittently to control signs of atopic dermatitis during sublingual (SL) or SC immunotherapy.
  - There is a lack of published data regarding the impact of any immunomodulator on the long-term outcome of allergen-specific immunotherapy in dogs.



**Safety studies have shown generalized demodicosis and bacterial pneumonia development in dogs receiving 3 to 5 times the label dose at 6 months of age.<sup>5</sup>**



**Safety of concurrent use of oclacitinib with other systemic immunomodulatory therapies has not been documented.**

- Concurrent use of systemic immunomodulators is cautioned.<sup>5</sup>



**No data support expectations of hematology, biochemistry, or urinalysis changes that could mandate monitoring.**

- Baseline diagnostic assessment before initiating long-term systemic immunomodulatory therapy is prudent.
  - In the author's opinion, annual monitoring of complete blood cell count, serum biochemistry, urinalysis, and urine culture is reasonable.
    - More frequent monitoring may be required for other diagnosed conditions.
- Urine culture every 6 to 12 months is worthy of consideration, as glucocorticoids and cyclosporine can predispose patients to UTIs.<sup>7,8</sup>
  - Occult UTI in patients chronically treated with oclacitinib has not been assessed.

## REFERENCES

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IL = interleukin, SL = sublingual, UTI = urinary tract infection