Sometimes an **itch**, is more than just an **itch**

**TELL ME ABOUT IT.**

Find out if your dog has allergic itch that may need medical treatment

APOQUELDOGS.COM
Dog itch may be a medical condition that needs treatment

All dogs itch sometimes. It’s natural. But when you notice it happening more and more, it could be a sign of a medical condition. Only your veterinarian can help determine if your dog’s itch is due to an infection, parasites, or allergies.

**SO DON’T WAIT...IF YOUR DOG IS ITCHING, TALK TO YOUR VETERINARIAN TODAY.**

It’s important to get to the underlying cause to help stop annoying and irritating itch, to give your four-legged friend some much-needed relief. Then they can get back to cuddling, playing, and sleeping in peace—without having to scratch all the time.

**Learn more about dog itch in this brochure.**

Your veterinarian can help get to the underlying cause of itching

**WHAT YOU SHOULD LOOK FOR:**

- Excessive licking, chewing, biting, or scratching
- Excessive rolling, rubbing, or scooting
- Foot chewing
- Hair loss
- Recurrent ear problems
- Changes in the skin, such as sores or darkened color
- Redness of the skin
- Body odor

If your dog’s itching persists or he or she exhibits any of the signs listed above, don’t wait. Itching can be a medical problem that needs attention.

Even though common at-home treatments such as oatmeal baths, lotions, or topical over-the-counter medicines may offer temporary relief of dog itch, they may not be getting to the root of the problem.

Your veterinarian will be able to tell you if a medical condition is the underlying cause, and whether a prescription medicine is required.

**Talk to your veterinarian today.**
APOQUEL® can help

IT'S A PRESCRIPTION TABLET THAT STOPS ALLERGIC ITCH—RIGHT AT THE SOURCE.

APOQUEL is a revolutionary medicine that works differently than other medicines. It goes right to the source—to stop the underlying cause of allergic itch in dogs 12 months and older.

FAST
APOQUEL starts relieving allergic itch in 4 hours—and controls it within 24 hours. 1,2

EFFECTIVE
APOQUEL works right at the source to stop itching and relieve inflammation. It is a prescription medicine used for the control of itch associated with allergic dermatitis and control of atopic dermatitis.

APOQUEL reduces dog itch and also decreases inflammation, redness, or swelling of the skin—so your dog feels better as quickly as possible.

SAFETY
• APOQUEL is safe to use in dogs 12 months of age and older
• APOQUEL can be used long-term for maintenance therapy

APOQUEL may be used with many other common therapies, including:
• Nonsteroidal anti-inflammatory drugs (NSAIDs; eg, carprofen)
• Vaccines (eg, rabies)
• Allergy shots or drops (eg, allergen-specific immunotherapy)
• Parasiticides
• Antifungals

The use of APOQUEL has not been evaluated in combination with other systemic immunosuppressants, such as corticosteroids and cyclosporine.

APOQUEL is not for use in dogs with serious infections, or for use in breeding, pregnant, or lactating dogs.

APOQUEL, an easy-to-administer tablet, is available only by prescription from your veterinarian.

Ask about APOQUEL today. Your dog will thank you!
Since APOQUEL is not a steroid, it does not have many of the side effects seen with steroids.

Did you know:

• 55% of dog owners report side effects with steroids

• The most common side effects of steroids are excessive drinking and urinating, excessive thirst and appetite

• APOQUEL works differently than steroids. In a short-term clinical trial, the most common side effects were vomiting and diarrhea and similar to those seen with placebo (sugar pills). These side effects occurred in only a small percentage of dogs treated with APOQUEL and typically stopped on their own

Weighing the side effects and the need for itch relief can feel like you are on an emotional roller coaster. But knowing the facts will help you and your dog’s veterinarian make the best choice for relief.

INDICATIONS
Control of pruritus (itching) associated with allergic dermatitis and control of atopic dermatitis in dogs at least 12 months of age.

IMPORTANT SAFETY INFORMATION
Do not use APOQUEL in dogs less than 12 months of age or those with serious infections. APOQUEL may increase the chances of developing serious infections, and may cause existing parasitic skin infestations or pre-existing cancers to get worse. APOQUEL has not been tested in dogs receiving some medications including some commonly used to treat skin conditions such as corticosteroids and cyclosporine. Do not use in breeding, pregnant, or lactating dogs. Most common side effects are vomiting and diarrhea. APOQUEL has been used safely with many common medications including parasiticides, antibiotics and vaccines.

For more information, please see the accompanying full Prescribing Information.

How to give APOQUEL® to your dog

APOQUEL COMES IN A CONVENIENT TABLET FORM.

Here’s how it’s administered:

• APOQUEL (oclacitinib tablet) can be given to your dog twice daily for up to 14 days. After 14 days, APOQUEL just needs to be administered once daily

• APOQUEL can be administered with or without food
**Dosage Chart**

<table>
<thead>
<tr>
<th>Weight Range (in lb)</th>
<th>Weight Range (in Kg)</th>
<th>Number of Tablets to be Administered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td>6.8</td>
<td>9.9</td>
<td>3.0</td>
</tr>
<tr>
<td>10.0</td>
<td>14.9</td>
<td>4.5</td>
</tr>
<tr>
<td>15.0</td>
<td>19.9</td>
<td>6.0</td>
</tr>
<tr>
<td>20.0</td>
<td>29.9</td>
<td>8.0</td>
</tr>
<tr>
<td>30.0</td>
<td>44.3</td>
<td>13.5</td>
</tr>
<tr>
<td>45.0</td>
<td>59.9</td>
<td>20.0</td>
</tr>
<tr>
<td>60.0</td>
<td>89.9</td>
<td>27.0</td>
</tr>
<tr>
<td>90.0</td>
<td>129.9</td>
<td>40.0</td>
</tr>
<tr>
<td>130.0</td>
<td>175.9</td>
<td>55.0</td>
</tr>
</tbody>
</table>

**Warnings:**
APOQUEL is not for use in dogs less than 12 months of age (see Animal Safety). APOQUEL is not for use in dogs with serious infections. APOQUEL may increase susceptibility to infection, including endocarditis, and exacerbate neoplastic conditions (see Adverse Reactions and Animal Safety).

**Human Warnings:**
This product is not for human use. Keep this and all drugs out of reach of children. For use in dogs only. Wash hands immediately after handling the tablets. In case of accidental eye contact, flush immediately with water or saline for at least 15 minutes and then seek medical attention. In case of accidental ingestion, wash hands immediately after handling the tablets. In case of accidental eye contact, flush immediately with water or saline for at least 15 minutes and then seek medical attention. In case of accidental ingestion, wash hands immediately after handling the tablets. In case of accidental ingestion, wash hands immediately after handling the tablets. In case of accidental ingestion, wash hands immediately after handling the tablets. In case of accidental ingestion, wash hands immediately after handling the tablets. In case of accidental ingestion, wash hands immediately after handling the tablets. 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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 APOQUEL (152 dogs: tablets administered at a dose of 0.4-0.6 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 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**

<table>
<thead>
<tr>
<th>Effectiveness Parameter</th>
<th>APOQUEL</th>
<th>Placebo</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Owner-Assessed Pruritus VAS</td>
<td>0.66 (n = 131)</td>
<td>0.04 (n = 133)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Veterinarian-Assessed CADESI</td>
<td>0.49 (n = 134)</td>
<td>0.04 (n = 134)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

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, 86.1% (127/147) of the placebo group dogs and 15% (23/150) of the APOQUEL group dogs withdrew from the masked study because of worsening clinical signs, and had the option to enroll 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.

**Margin of Safety in 12 Month Old Dogs**

Oclacitinib maleate was administered to healthy, one-year-old Beagle dogs twice daily for 6 weeks, 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 papillomas and a dose-dependent increase in the number and frequency of interdigital furunculosis (cysts) on one or more feet during the study. 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 node; 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 basophils. Total proteins were decreased over time primarily due to the albumin fraction.

**Vaccine Response Study**

An adequate immune response (serology) to killed rabies (RV), modified live canine distemper virus (CDV), and modified live canine parainfluenza virus (CPV) vaccination was achieved in eight 16-week old vaccine naïve 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 (CPV), < 80% (6 of 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 lesions consistent with sepsis secondary to immunosuppression. Bone marrow hyperplasia was consistent with response to sepsis.

**Margin of Safety in 6 Month Old Dogs**

A margin of safety study in 6-month-old dogs was discontinued after four months due to the development of bacterial pneumonia and generalized demodex mange infections in dogs in the high dose (3X and 5X) treatment groups, dosed at 1.8 and 3.0 mg/kg oclacitinib twice daily, for the entire study.

**Storage Conditions:**

APOQUEL should be stored at controlled room temperature between 20° to 25°C (68° to 77°F) with excursions between 15° to 40°C (59° to 104°F).

**How Supplied:**

APOQUEL tablets contain 3.6 mg, 5.4 mg, or 16 mg of oclacitinib as oclacitinib maleate per tablet. Each strength tablets are packaged in 20 and 100 count bottles. Each tablet is scored and marked with AQ and either an S, M, or L that correspond to the different tablet strengths on both sides.

**NADA #141-345, Approved by FDA**

Made in Italy

**Distributed by:**

Zoetis Inc.

Kalamazoo, MI 49007

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