See How Apoquel Helps Dogs With Allergic Itch Get Fast Relief

Itching like a dog is bothering me!

Next to You, Apoquel Is a Dog's Best Friend
If Your Dog’s Itching Like Crazy, Ask for Apoquel

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

When Is an Itch More Than Just an Itch?

It’s important to get to the underlying cause of itch to avoid additional skin problems and to help your dog enjoy life again—without having to scratch all the time. So don’t wait—talk to your vet today.

Common Signs of Allergic Itch

- Frequent scratching, licking, biting, or chewing
- Excessive rolling, rubbing, or scooting
- Recurrent ear problems: head shaking, ear discharge, or scratching at the ears
- Hair loss, body odor, or skin changes: rash, redness, greasy skin, or scabs

If your dog’s itching persists or if he or she exhibits any of the signs 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.

“Help! I’m itching like crazy!”

Talk to Your Veterinarian Today

Next to You, Apoquel Is a Dog’s Best Friend
Apoquel is a revolutionary medicine that works differently than other medicines. It’s a prescription tablet that goes right to the source—to stop the underlying cause of allergic itch in dogs 12 months of age and older.

**Fast**
Starts relieving allergic itch in 4 hours, and controls it within 24 hours\(^1,2\)

**Effective**
Works right at the source to stop itching and relieve inflammation in dogs. Apoquel reduces dog itch and also decreases inflammation, redness, or swelling of the skin—so your dog feels better as quickly as possible.

**Safe**
Can be used for long-term maintenance therapy or short-term therapy in dogs 12 months of age and older\(^3,4\)

**Daily Pill**
Given with or without food, and available with a prescription from your veterinarian.

Apoquel May Be Used With Many Other Common Therapies, Including\(^3\):
- 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.
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. 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 has 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 has been used safely with many common medications including parasiticides, antibiotics and vaccines.

See Accompanying Full Prescribing Information.

“Wow—rewards, too?!”

With each eligible Apoquel purchase, earn up to $100 in Rewards to pay for future vet care.

Sign up for Zoetis Petcare Rewards* and see full offer details at zoetispetcare.com/rewards

*Program Terms and Conditions apply.

To learn more about Apoquel, scan code with your smart phone or visit apoqueldogs.com

Talk to Your Veterinarian Today

Next to You, Apoquel Is a Dog’s Best Friend

ZOETIS PETCARE

All trademarks are the property of Zoetis Services LLC or a related company or a licensor unless otherwise noted. © 2021 Zoetis Services LLC. All rights reserved. APQ-01170
**Adverse Reactions:**

**Control of Atopic Dermatitis:**

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 lumps (2.6% APOQUEL, 2.7% placebo), and lethargy (2.6% APOQUEL, 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-up of dermatitis and severe secondary pyoderma after 19 days of APOQUEL administration, 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 urolithiasis (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): pyoderma (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%).

**Control of Pruritus Associated with Atopic Dermatitis:**

In a masked field study to assess the effectiveness and safety of oclacitinib for the control of pruritus associated with atopic dermatitis in dogs, 216 dogs treated with APOQUEL and 220 dogs treated with placebo (vehicle control) were evaluated for safety. During the 30-day study, there were no fatalities and no adverse reactions requiring hospital care. Adverse reactions reported (and percent of dogs affected) during Days 0-7 included diarrhea (2.3% APOQUEL, 0.9% placebo), vomiting (2.3% APOQUEL, 1.8% placebo), lethargy (1.8% APOQUEL, 1.4% placebo), anorexia (1.4% APOQUEL, 0% placebo), and polydipsia (1.4% APOQUEL, 0% placebo). In most of these cases, signs spontaneously resolved with continued dosing. Five APOQUEL 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 APOQUEL 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 APOQUEL group increased at Day 7, but returned to pretreatment levels by study end without a break in APOQUEL administration. Serum cholesterol increased in 25% of APOQUEL group dogs, but mean cholesterol remained within the reference range.

**Continuation Field Study:**

After completing APOQUEL field studies, 239 dogs enrolled in an unmasked (no placebo control) continuation therapy study receiving APOQUEL for an unrestricted period of time. Mean time on this study was 372 days (range 1 to 610 days). Of these dogs, one dog developed demodicosis following 273 days of APOQUEL administration. One dog developed dermal pigmented viral plaques following 266 days of APOQUEL administration. One dog developed a moderately severe bronchopneumonia after 272 days of APOQUEL administration; this infection resolved with antimicrobial treatment and temporary discontinuation of APOQUEL. One dog was euthanized after developing abdominal ascites and pleural effusion of unknown etiology after 450 days of APOQUEL 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 APOQUEL administration, respectively. Two dogs each developed a Grade II mast cell tumor after 52 and 91 days of APOQUEL administration, respectively. One dog developed a low grade B-cell lymphoma after 392 days of APOQUEL administration. Two dogs each developed an approximated grade 2 adenoma (one dermal, one anal sac) after approximately 210 and 320 days of APOQUEL administration, respectively. One dog developed a low grade oral spindle cell sarcoma after 320 days of APOQUEL administration.

**Post-Approval Experience (2020):**

The following adverse events are based on post-approval adverse drug experience reporting for APOQUEL. 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, pododermatitis, pyoderma), seizures, polydipsia, and demodicosis. Benign, malignant, and unclassified neoplasms, dermal masses (including papillomas and histiocytomas), 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.
Veterinarians assessed dermatitis scores continued to improve through study end at Day 30. 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) compared with the placebo group mean score of 4.9 cm (from a baseline value of 6.2 cm). For dogs that continued APOQUEL treatment beyond one week, theVeterinarian-assessed dermatitis scores continued to improve through study end at Day 30.

### Effectiveness: Control of Atopic Dermatitis

A double-masked, 30-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 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.

Mean (95% CI) total body oclacitinib clearance from plasma was low – 316 (237, 396) mL/h/kg body weight (3.3 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:**

**Owner-Assessed Pruritus VAS**

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 at 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 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></th>
<th>APOQUEL</th>
<th>Placebo</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Owner-Assessed Pruritus VAS</td>
<td>0.66</td>
<td>0.04</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>(n = 131)</td>
<td>(n = 133)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Veterinarian-Assessed CADESI</td>
<td>0.49</td>
<td>0.04</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>(n = 134)</td>
<td>(n = 134)</td>
<td></td>
<td></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 in the APOQUEL group compared to the placebo group.

**Estimated Proportion of Dogs with Treatment Success, Atopic Dermatitis**

<table>
<thead>
<tr>
<th></th>
<th>APOQUEL</th>
<th>Placebo</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.67</td>
<td>0.29</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

After one week of treatment, 86.4% of APOQUEL 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 APOQUEL 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 APOQUEL 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 APOQUEL treatment beyond one week, the veterinarians’assessed dermatitis scores continued to improve through study end at Day 30.