Canine Atopic Dermatitis Immunotherapeutic*

ADVANCING THE SCIENCE OF ATOPIC DERMATITIS TREATMENT

Welcome to the Canine Atopic Dermatitis Immunotherapeutic* Conditional Licensing Program!

Now a once-monthly,† in-office injection can help improve the long-term quality of life for both dogs with atopic dermatitis and their owners

LONG-LASTING
Canine Atopic Dermatitis Immunotherapeutic* is injected in-office, ensuring compliance. It begins working within 1 day and delivers a full month of relief.¹

TARGETED
Canine Atopic Dermatitis Immunotherapeutic* is a caninized anti-cIL-31 monoclonal antibody (mAb) specifically designed to target interleukin (IL)-31, a key cytokine involved in sending the itch signal to the brain.²

SAFE
Safe for dogs of all ages³ and can be used concurrently with many common medications, including parasiticides, antibiotics, antifungals, corticosteroids, vaccines, immunotherapy, antihistamines and other antipruritics, such as oclacitinib and cyclosporine.⁴

Indication
Canine Atopic Dermatitis Immunotherapeutic* aids in the reduction of clinical signs associated with atopic dermatitis in dogs.

*This product license is conditional. Efficacy and potency test studies in progress.
†Repeat administration monthly, as needed.
Canine Atopic Dermatitis Immunotherapeutic®

How does Canine Atopic Dermatitis Immunotherapeutic® work?
Canine Atopic Dermatitis Immunotherapeutic® is a ready-to-use, sterile liquid containing caninized anti-cIL-31 monoclonal antibody (mAb). This mAb specifically targets and neutralizes canine interleukin (IL)-31, which is involved in sending the itch signal to the brain.² By targeting the IL-31 pathway, Canine Atopic Dermatitis Immunotherapeutic® interrupts the cycle of itch and inflammation in dogs with atopic dermatitis.

What is the indication for Canine Atopic Dermatitis Immunotherapeutic®?
Canine Atopic Dermatitis Immunotherapeutic® aids in the reduction of clinical signs associated with atopic dermatitis in dogs.

How long does Canine Atopic Dermatitis Immunotherapeutic® remain in the body?
Canine Atopic Dermatitis Immunotherapeutic® remains in circulation for several weeks.¹ Like other naturally occurring antibodies and antibody-antigen complexes, it is eliminated via normal protein degradation pathways.

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Canine Atopic Dermatitis Immunotherapeutic*

DEMONSTRATED EFFICACY IN REDUCING PRURITUS

A single injection begins reducing itch within 1 day, continues working for a full month

OVER 80% HAD SUCCESSFUL PRURITUS REDUCTION AT DAY 3

At day 3, greater than 80% of dogs administered Canine Atopic Dermatitis Immunotherapeutic* achieved treatment success, predefined as owner-assessed ≥20-mm reduction in pruritus as scored on the pruritus Visual Analog Scale (VAS).†

Mean pruritus scores were very mild to mild starting at day 1 and continuing for a full month

At day 42, owner assessment of pruritus VAS scores remained mild at 37.6 mm (mean baseline: 71.0 mm) for dogs receiving a 2 mg/kg dose of Canine Atopic Dermatitis Immunotherapeutic.‡

**Study Design:**
In a study of canine patients presented to veterinary hospitals and diagnosed with atopic dermatitis, a single dose of Canine Atopic Dermatitis Immunotherapeutic* (2.0 mg/kg) or placebo was administered subcutaneously on day 0. Fifty dogs received 2.0 mg/kg of Canine Atopic Dermatitis Immunotherapeutic* and 52 dogs received placebo. Treatment success measures were based on owner assessment of pruritus using the pruritus Visual Analog Scale (VAS).†

†VAS is an owner-assessed scale that measures itch along a continuum from normal dog (no itch) to extremely severe itch, using numbers from 0-100. VAS scoring instruments were given to owners, accompanied by explanations of how to rank itch based on the behavior of the animal. Owners ranked itch daily.

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DEMONSTRATED EFFICACY IN IMPROVING SKIN CONDITION

**Begins to improve skin condition within 7 days**

**SKIN CONDITION SCORE REDUCTION WAS SIGNIFICANT AT DAY 14**

In a clinical trial, a single dose of Canine Atopic Dermatitis Immunotherapeutic* demonstrated significantly greater efficacy vs placebo in achieving 50% reduction from baseline in veterinarian-assessed skin condition for 1 month (p≤0.05) (mean baseline for all dogs: 153.9).1

**Skin condition score reduction was maintained through day 28**

Significant improvement in skin condition was noted at the first visit on day 7 (p≤0.05). At day 28, there was a nearly 50% decrease in CADESI-03 dermatologist scores for dogs administered Canine Atopic Dermatitis Immunotherapeutic* (73.7) compared to dogs administered placebo (121.9) (mean baseline for all dogs, 153.9).1

**Study Design:**

In a study of canine patients presented to veterinary hospitals and diagnosed with atopic dermatitis, a single dose of Canine Atopic Dermatitis Immunotherapeutic* (2.0 mg/kg) or placebo was administered subcutaneously on day 0. Fifty dogs received 2.0 mg/kg of Canine Atopic Dermatitis Immunotherapeutic* and 52 dogs received placebo. Treatment success measures were based on veterinarian assessment of skin condition scores using the Canine Atopic Dermatitis Extent and Severity Index (CADESI-03).1

1Canine Atopic Dermatitis Extent and Severity Index. CADESI-03 skin condition assessment consisted of an evaluation of erythema, lichenification, excoriation and alopecia at 62 body sites.

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**WELL TOLERATED AND SAFE**

**Side effects were minimal, manageable and similar to placebo**

In a study of dogs that were administered Canine Atopic Dermatitis Immunotherapeutic,* the most common side effects were vomiting, diarrhea and lethargy. In a separate study, these abnormal health events were self-limiting and not continuous through the length of the study.4

**Field study results showed adverse events comparable to placebo**

Most common abnormal health events4

<table>
<thead>
<tr>
<th>Abnormal health event preferred term</th>
<th>Placebo (83 dogs) % (N)</th>
<th>Canine Atopic Dermatitis Immunotherapeutic* (162 dogs) % (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Otitis externa</td>
<td>12.0 (10)</td>
<td>13.0 (21)</td>
</tr>
<tr>
<td>Dermatitis</td>
<td>13.3 (11)</td>
<td>9.9 (16)</td>
</tr>
<tr>
<td>Bacterial skin infection</td>
<td>12.0 (10)</td>
<td>9.3 (15)</td>
</tr>
<tr>
<td>Erythema</td>
<td>4.8 (4)</td>
<td>8.0 (13)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>10.8 (9)</td>
<td>7.4 (12)</td>
</tr>
<tr>
<td>Anorexia</td>
<td>4.8 (4)</td>
<td>6.2 (10)</td>
</tr>
<tr>
<td>Lethargy</td>
<td>6.0 (5)</td>
<td>5.6 (9)</td>
</tr>
<tr>
<td>Pruritus</td>
<td>19.3 (16)</td>
<td>4.9 (8)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>4.8 (4)</td>
<td>3.7 (6)</td>
</tr>
<tr>
<td>Alopecia</td>
<td>7.2 (6)</td>
<td>2.5 (4)</td>
</tr>
</tbody>
</table>

*Occurrence was calculated on a per-case basis—no matter how many observations of the same abnormal health event a dog had, it contributed one observation to the occurrence calculation.

**CONCOMITANT MEDICATIONS**

A wide variety of concomitant medications were safely used, including parasiticides, antibiotics, antifungals, corticosteroids, vaccines, immunotherapy, antihistamines and other antipruritics, such as oclacitinib and cyclosporine.4

**LONG-TERM SAFETY**

Canine Atopic Dermatitis Immunotherapeutic* has been demonstrated to be well tolerated in a laboratory safety study in which 7 consecutive monthly subcutaneous injections were administered to laboratory Beagles at doses of 3.3 mg/kg or 10 mg/kg body weight (12 dogs per group).3

**HOW TO USE CANINE ATOPIC DERMATITIS IMMUNOTHERAPEUTIC**

**How supplied**

Canine Atopic Dermatitis Immunotherapeutic* is available in 1-mL vials in four concentrations (10, 20, 30 or 40 mg).

**Dosage and administration**

Administer Canine Atopic Dermatitis Immunotherapeutic* by subcutaneous injection at a minimum dose of 2 mg/kg body weight according to the dosing table. Repeat administration monthly, as needed.

**Dosing chart**

- **Dogs <5 lb (2.3 kg):**
  - 0.09 mL/lb (0.2 mL/kg) drawn from ONE 10-mg vial.
  - Dogs requiring 1 vial
  - Dogs > 5 lb (2.3 kg):
    - Draw the entire dose into one syringe and administer as a single injection.

- **Dogs 5-40 lb (2.3-18.1 kg):**
  - Full volume drawn from ONE 1-mL vial as indicated.
  - Dogs requiring 1 vial
  - Dogs > 40 lb (18.1 kg):
    - Full volume of TWO OR MORE 1-mL vials as indicated.
    - Dogs requiring 2 or more vials

**Storage**

The product does not contain a preservative. Each vial is for single use only and should be discarded after puncture. Store upright at 2°-8°C. Prolonged exposure to higher temperatures and/or direct sunlight may adversely affect potency. Do not freeze.

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INTRODUCING THE CONDITIONAL LICENSING PROGRAM

What is the Conditional Licensing Program?
The Conditional Licensing Program provides early access to the product for a select group of invited veterinarians. You have been chosen for this program because we respect your opinion and expertise in the field of veterinary dermatology.

We are eager to hear about your experience with Canine Atopic Dermatitis Immunotherapeutic.* Your valuable feedback will help us gather important clinical information and allow us to be better prepared when we launch this new treatment to the entire veterinary community.

What can the Conditional Licensing Program do for my practice?
This innovative new treatment will allow you to provide your patients with sustained and safe relief of the clinical signs of atopic dermatitis, helping you improve the long-term quality of life for both dogs with atopic dermatitis and their owners.

How does the Conditional Licensing Program work?

1. During the conditional license program, you will have the opportunity to purchase Canine Atopic Dermatitis Immunotherapeutic.* Please administer this product to dogs suffering from atopic dermatitis.

2. You can purchase the product by calling 877-682-2369 or emailing canineIL31@zoetis.com.

3. In addition, you will receive a starter pack of Canine Atopic Dermatitis Immunotherapeutic* (one 2-pack of each SKU). In return for these samples, please visit www.experienceIL31.com to provide feedback on your success with Canine Atopic Dermatitis Immunotherapeutic.*

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WE WANT TO HEAR ABOUT YOUR SUCCESS WITH CANINE ATOPIC DERMATITIS IMMUNOTHERAPEUTIC!* 

How to share your patients’ success: 

• After several of your patients have achieved treatment success with Canine Atopic Dermatitis Immunotherapeutic,* go to www.experienceIL31.com and fill out the survey there.

We want to hear from your clients about their success too! 

• Ask your clients to visit www.experienceIL31.com four weeks after their dog begins treatment to complete a survey about their dog’s success with Canine Atopic Dermatitis Immunotherapeutic.*

• Encourage them to upload videos showing how their dog has been able to enjoy favorite activities again, thanks to getting sustained relief of the clinical signs of atopic dermatitis with Canine Atopic Dermatitis Immunotherapeutic.*

Questions about the Conditional Licensing Program? 

If you have any questions about Canine Atopic Dermatitis Immunotherapeutic* or the Conditional Licensing Program, call 877-682-2369 or email caninel31@zoetis.com.

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