

Prescription Label

Patient Name:

Species:

Drug Name & Strength:

Directions (amount to give how often & for how long):

Prescribing Veterinarian's Name & Contact Information:

Refills:

[Content to be provided by prescribing veterinarian]

Oclacitinib

(*ok-la-sit-ti-nib*)

Description:

Anti-Itch and Anti-Inflammatory Agent

Other Names for this Medication:

Apoquel[®]

Common Dosage Forms:

Veterinary: 3.6 mg, 5.4 mg, and 16 mg tablets. **Human:** None.

This information sheet does not contain all available information for this medication and has not been reviewed by FDA Center for Veterinary Medicine. This sheet can help answer commonly asked questions but is not a substitute for medical advice. If you have other questions or need more information about this medication, contact your veterinarian or pharmacist.

Key Information

- Oclacitinib works quickly. Many animals show improvement within 24 hours of starting treatment.
- This medicine is typically well tolerated.
- Oclacitinib may increase the risk for infections. Be sure to tell your veterinarian if your animal has a history of infections.
- Contact your veterinarian if new skin masses appear or if existing masses grow larger.
- Your veterinarian will need to monitor your animal while it is taking this medicine. Do not miss these important follow-up visits.
- This medication is usually given twice a day for up to 14 days, then decreased to once a day.
- Wash hands immediately after handling tablets.

How is this medication useful?

The FDA (U.S. Food & Drug Administration) has approved this medicine for use in dogs that are at least 1 year of age for treating itch associated with allergic dermatitis, including flea allergies and atopic dermatitis. The FDA allows veterinarians to prescribe and use products containing this medication in different species or for other conditions in certain situations. You and your veterinarian can discuss why this medicine is the most appropriate choice.

What should I tell my veterinarian to see if this medication can be safely given?

Many things might affect how well this medication will work in your animal. Be sure to discuss the following with your veterinarian so together you can make the best treatment decisions.

- Other medications may interact with this medication, so be sure to tell your veterinarian and pharmacist what medications (including vitamins, supplements, or herbal therapies) you give your animal, including the amount and time you give each.
- Tell your veterinarian about any conditions (eg, infections, skin masses) or diseases your animal may have now or has had in the past.
- If your animal has been treated for the same disease or condition in the past, tell your veterinarian about the treatment and how well it did or did not work.
- If your animal is pregnant or nursing, talk to your veterinarian about the risks of using this medicine.
- Tell your veterinarian and pharmacist about any medication side effects (including allergic reactions, lack of appetite, diarrhea, itching, hair loss) your animal has developed in the past.

How long until I will know if this medication is working, and how long will the effects of this medication last?

This medication should help your animal feel better within 1 to 2 days. Your animal's clinical signs should improve after that time. The effects of this medication are short-lived, meaning it will stop working within 24 hours.

When should this medication not be used or be used very carefully?

No medicine is 100% safe in all patients, but your veterinarian will discuss with you any specific concerns about using this medicine in your animal.

This drug **SHOULD NOT** be used in patients:

- That are allergic to it.
- With serious infections.
- That are less than 12 months old.
- That are used for breeding or are pregnant or lactating.

This drug should be used **WITH CAUTION** in patients:

- With ongoing infections.

If your animal has any of these conditions, talk to your veterinarian about the potential risks versus benefits.

What are the side effects of this medication?

Side effects commonly reported that usually are not serious include:

- Vomiting, diarrhea, lack of appetite
- Increased thirst
- Low energy level, tiredness

If any of these signs are severe, worsen, or continue to be a problem, contact your veterinarian.

Side effects that may be serious or indicate a serious problem:

- Infection. Oclacitinib may increase your animal's risk for infection. Watch for signs of infection such as fever (103°F-104°F), frequent or painful urination, tiredness or lack of energy, coughing, or poor appetite.
- Any new growths or an enlargement of existing skin masses
- Rash or oozing sores

If you see any of these signs, contact your veterinarian immediately.

If my animal gets too much of this medication (an overdose), what should I do?

If you witness or suspect an overdose, contact your veterinarian or an animal poison control center for further advice. Animal poison control centers open 24 hours a day include: **Pet Poison HELPLINE** (855-764-7661) and **ASPCA Animal Poison Control Center** (888426-4435); a consultation fee may be charged for these services.

How should this medication be given?

For this medication to work properly, give it exactly as your veterinarian has prescribed. Check the prescription label to be sure you are giving the medication correctly.

- This medication may be given either with food or on an empty stomach. If your animal vomits or acts sick after receiving the medication on an empty stomach, try giving the next dose with food or a small treat. If vomiting continues, contact your veterinarian.

- If you have difficulty getting your animal to take this medication, contact your veterinarian or pharmacist for tips to help with dosing and reducing the stress of medication time for both you and your animal. Do not crush the tablets.
- This medication can be given for various lengths of time. Be sure you understand how long your veterinarian wants you to continue giving this medication. Prescription refills may be necessary before the therapy will be complete. If you want to stop giving this medication, talk to your veterinarian, as there may be important reasons to continue giving it.

What should I do if I miss giving a dose of this medication?

If you miss a dose, give it as soon as you remember unless it is almost time for the next dose. If the next dose is due within a few hours, skip the missed dose and give at the next scheduled time. After that, return to the regular dosing schedule. Do not double-up or give extra doses.

How should I store this medication?

- Store this medication in the original prescription bottle or an approved dosage reminder container (such as a pill organizer) at room temperature.
- Keep away from children and other animals.

Can handling this medication be hazardous to me, my family, or other animals?

- Pregnant women and people who are allergic to this medication should be careful not to accidentally take it.
- Since this medication has the potential to decrease white blood cell counts in animals, it is recommended that any caregivers handling the medication wash their hands immediately after medicating the animal as a precaution.
- In the case of accidental eye contact, flush immediately with water or saline for at least 15 minutes and then seek medical attention. This medicine may cause inflammation of the eyes (ie, conjunctivitis) if it comes into contact with the eye.
- In case of accidental ingestion, seek medical attention immediately.

How should I dispose of this medication if I don't use it all?

- Do not flush this medication down the toilet or wash it down the sink. If a community medicine “take-back” program is available, use this option. If there is no take-back program, mix the medication with coffee grounds or cat litter (to make it undesirable to children and animals and unrecognizable to people who might go through your trash), place the mixture in a sealable plastic bag to keep it from leaking out, and throw the bag out with the regular trash.
- Do not save leftover medication for future use or give it to others to use.

What other information is important for this medication?

- Use of this medication may not be allowed in certain animal competitions. Check rules and regulations before entering your animal in a competition while this medication is being administered.
- Your veterinarian will need to monitor your animal while it is taking this medicine. Do not miss these important follow-up visits.

If you have any other questions about this medication, contact your veterinarian or pharmacist.