

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 & Anti-Inflammatory Agent

Other Names for this Medication:

Apoquel®

Common Dosage Forms:

Veterinary: 3.6 mg, 5.4 mg, & 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

- ▶ Because oclacitinib is a new medication, be sure to report any unexpected side effects to your veterinarian.
- ▶ Oclacitinib works quickly. Many dogs show improvement within the first few days of treatment.
- ▶ The most commonly reported side effects are vomiting, diarrhea, lack of appetite, increased thirst, and lethargy.
- ▶ Serious side effects, including increased risk of infections and skin disorders, are possible.
- ▶ This medication is usually given twice a day for the first 2 weeks 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 drug for use in dogs that are at least 1 year of age for treating itch associated with allergic dermatitis and for controlling signs caused by atopic dermatitis. The FDA allows veterinarians to prescribe and use products containing this drug in different species or for other conditions in certain situations. You and your veterinarian can discuss why this drug 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 drug will work in your animal. Be sure to discuss the following with your veterinarian so together you can make the best treatment decisions.

- ▶ Other drugs 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 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 drug.
- ▶ 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 they will stop working within 24 hours, although the benefits may be prolonged if your animal has decreased kidney and/or liver function.

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

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

Due to its recent approval and limited clinical use, oclacitinib's adverse effect profile is not fully known.

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:

- ▶ Increased possibility of infections. Watch for signs of infection including poor appetite, low energy level, high fever.
- ▶ Any new growths seen on your animal.
- ▶ Skin disorders, such as a 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** (888-426-4435); 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 drug correctly.

- ▶ The drug may be given either with food or on an empty stomach. If your animal vomits or acts sick after receiving the drug on an empty stomach, try giving the next dose with food or a small treat. If vomiting continues, contact your veterinarian.
- ▶ Compounded liquid forms of this medication must be measured carefully. Your veterinarian or pharmacist can help by providing special measuring spoons or syringes.
- ▶ If you have difficulty getting your animal to take the medicine, contact your veterinarian or pharmacist for tips to help with dosing and reduce the stress of medication time for both you and your animal.
- ▶ 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 when you remember, but if it is close enough to the time for the next dose, skip the dose you missed and give it 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 (ie, pill minder) at room temperature and protected from light.
- ▶ If your veterinarian or pharmacist has prepared (compounded) a special formulation for your animal, follow the storage recommendations and expiration date for the product.
- ▶ 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 drug should be careful not to accidentally take it.
- ▶ Skin or eyes exposed to powder or liquids containing the drug should immediately be washed or rinsed off thoroughly. In the case of accidental eye contact, flush immediately with water or saline for at least 15 minutes and then seek medical attention. This drug 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 drug “take-back” program is available, use this option. If there is no take-back program, mix the drug 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 drug 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.

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

Special Instructions:
