

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]

Orbifloxacin

(*or-bi-flox-a-sin*)

Description:

Fluoroquinolone Antibiotic

Other Names for this Medication:

Orbax[®]

Common Dosage Forms:

Veterinary: 22.7 mg & 68 mg tablets; 30 mg/mL oral suspension. **Human:** None.

Antimicrobial Classification:

Critically Important

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

- Orbifloxacin is best given without food on an empty stomach, but if your animal vomits or acts sick after getting it, give with small amount of food or small treat (no dairy products, antacids, or anything containing iron) to see if this helps. If vomiting continues, contact your veterinarian.
- Do not give at the same time with other drugs or vitamins that contain calcium, iron, or aluminum (including sucralfate), as these can reduce the amount of drug absorbed.
- Most common side effects are vomiting, nausea, or diarrhea.
- May cause joint abnormalities if used in young animals, during pregnancy, or while nursing.
- Complete the entire course of antibiotics prescribed by your veterinarian even if your animal appears well.

How is this medication useful?

The FDA (U.S. Food & Drug Administration) has approved this drug for use in dogs and cats for treating skin, respiratory tract, and urinary tract infections. The FDA allows veterinarians to prescribe and use products containing orbifloxacin 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 can interact with orbifloxacin, 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 didn't 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 start having effects within 1 to 2 hours; however, you may not see the effects of this medication outwardly. Your animal should begin feeling better within 1 to 2 days. 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:

- Animals that are allergic to it or drugs like it (eg, enrofloxacin).
- Young dogs: Between 2-8 months old in small and medium-sized breeds and up to 18 months old in large and giant breeds.
- Animals that are pregnant or nursing unless the benefits to the mother outweigh the risks to offspring.

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

- With a history of epilepsy or seizures.
- That have liver or kidney problems.
- That are dehydrated.

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 that usually are not serious include:

- Vomiting, diarrhea, nausea, reduced appetite.

You don't have to be overly concerned if you see any of these effects unless they are severe, worsen, or continue to be a problem. Contact your veterinarian if this happens.

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

- Trouble walking (or other joint effects), especially in young or growing animals.
- Stimulation (eg, overly excited) or seizures (rare), especially in animals with liver or kidney problems.
- Blindness in cats can be caused by large doses.
- Fever, rashes, or trouble breathing may indicate an allergy to the drug.
- Decreased or lack of an appetite, especially in cats.

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?

Overdoses of orbifloxacin could be serious. If you witness or suspect an overdose, contact your veterinarian or an animal poison control center for further advice. Animal poison control centers that are open 24 hours a day include: **Pet Poison HELPLINE** (855-764-7661) and **ASPCA Animal Poison Control Center** (888-426-4435); a consultation fee is charged for these services.

How should this medication be given?

For this medication to work, give it exactly as your veterinarian has prescribed. It's a good idea to always check the prescription label to be sure you are giving the drug correctly.

- This drug is best given without food on an empty stomach, but if your animal vomits or acts sick after getting it, give with food or small treat (no dairy products, antacids, or anything with iron) to see if this helps. If vomiting continues, contact your veterinarian.
- Do not give orbifloxacin at the same time with other drugs containing calcium, iron, or aluminum (including antacids and sucralfate) as these can reduce the amount of drug absorbed.
- Liquid forms of this medication must be measured carefully and should be shaken well before each dose. Your veterinarian or pharmacist can help by providing special measuring spoons or syringes. Liquid forms of this drug should be discarded on the day your veterinarian or pharmacist has indicated.
- If you have difficulty getting your animal to take the medicine, contact your veterinarian or pharmacist for tips to help with dosing and reducing the stress of medication time.
- 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. Before stopping this medication, talk to your veterinarian, as there may be important reasons to continue its use.

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 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 all forms of this medication in their original prescription bottle or an approved dosage reminder (ie, pill minder) container at room temperature and protected from light.
- If your veterinarian or pharmacist has made (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?

There are no specific precautions required when handling this medication unless you are allergic to it. Wash your hands after handling any medication.

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?

- This drug is banned from use in food animals.
- Do not use in humans.
- 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
