

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]

Ketoconazole

(*kee-toe-kah-na-zole*)

Description:

Antifungal

Other Names for this Medication:

Nizoral®

Common Dosage Forms:

Veterinary: None. **Human:** 200 mg oral tablets (scored); topical products also available.

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

- ▶ Give ketoconazole with high-fat foods (eg, cheese, cream, butter) to increase absorption.
- ▶ Gastrointestinal effects (eg, lack of appetite, vomiting, diarrhea) are the most common side effects, especially in cats.
- ▶ Watch for persistent vomiting, poor appetite, yellowing of gums or whites of the eyes (jaundice). If these signs are seen, stop giving the drug and contact your veterinarian immediately as liver toxicity is possible.
- ▶ Only use ketoconazole when absolutely necessary in pregnant or breeding animals, as this drug may cause birth defects in animals and reduce fertility in males.
- ▶ This drug has many drug interactions; do not start new medications without first checking with your veterinarian or pharmacist.
- ▶ **Pregnant women should use caution when handling.**

How is this medication useful?

Ketoconazole is used to treat fungal infections in animals; it can also be used to allow reduced dosages of certain other drugs (eg, cyclosporine). The FDA (U.S. Food & Drug Administration) has approved this drug for use in humans, but it is not officially approved for

use in animals. The FDA allows veterinarians to prescribe 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 can interact with this drug, 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 takes several doses before you will see any effect. The medication's full effects may not be evident until your animal has taken it consistently for several weeks, but you will see a gradual improvement of your animal's clinical signs until the medication becomes fully effective. The effects of this medication are moderate in duration, meaning they may last for a few days, 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 or other azole antifungals (eg, itraconazole, fluconazole).

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

- ▶ That have liver disease.
- ▶ That have too few platelets.
- ▶ That are pregnant or nursing or in male animals used for breeding. Ketoconazole has caused birth defects in rodents and stillbirths in dogs. It can also reduce fertility in male animals.

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:

- ▶ Decreased appetite, vomiting, and diarrhea are the most common side effects. While this may not be serious, your veterinarian may wish for you to contact them if they occur. Cats are more likely to have more severe gastrointestinal problems than dogs.
- ▶ Change in fur color. Some animals' coats become lighter in color while on this medication. The coat should return to normal color when the drug is stopped.

You don't have to be overly concerned if you see any of these signs 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:

- ▶ Persistent vomiting, diarrhea, loss of appetite, yellowing of eyes, skin, or gums (jaundice), tender or painful abdomen (stomach), bleeding, seizures (convulsions), or severe changes in behavior may indicate liver toxicity or other organ failure (eg, adrenal glands) caused by ketoconazole.
- ▶ Cataracts (in dogs; rare).

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 that are open 24 hours a day include: **ASPCA Animal Poison Control Center** (888-426-4435) and **Pet Poison HELPLINE**

(855-764-7661); 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.

- ▶ Ketoconazole should be given with food. Giving it with a fatty food such as butter, cream, or cheese helps the drug to be absorbed.
- ▶ Antacids and medications that reduce stomach acid (eg, ranitidine) should be avoided while your animal is receiving ketoconazole. If the animal must receive these drugs, they should not be given until 2 hours after the ketoconazole is given.
- ▶ 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 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 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 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?

- ▶ Pregnant women and people who are allergic to this drug should be very careful not to accidentally take it. Because this drug has a higher risk for causing birth defects, pregnant women should take extra care to wear disposable gloves when handling the drug and avoid inhaling any dust from split or crushed tablets. Skin or eyes exposed to powder or liquids containing ketoconazole should immediately be washed or rinsed off thoroughly.
- ▶ 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?

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
