

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]

Ursodiol

(ur-soe-**dve**-ole)

Description:

Bile Acid

Other Names for this Medication:

Actigall®, Ursodeoxycholic acid

Common Dosage Forms:

Veterinary: None. Human: 300 mg oral capsules; 250 mg & 500 mg oral tablets.

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

- Ursodiol works best when given with food.
- Usually well tolerated by dogs and cats.
- Used to help animals with cholesterol-containing gallstones and/or chronic liver disease.
- ▶ Do not give to rabbits, guinea pigs, or rodents.

How is this medication useful?

Ursodiol is used to help animals with certain types of gallstones and inflammation associated with the gall bladder. Ursodiol has also been shown to be useful to minimize inflammation associated with chronic liver disease. The FDA (U.S. Food & Drug Administration) has approved this drug for use in humans. Ursodiol is not officially approved for use in animals; however, 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 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 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 days; however, you will not see the effects of this medication outwardly. Your veterinarian will need to run further tests to determine if the medication is working appropriately. 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.
- In rabbits, guinea pigs, or rodents.

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

▶ With complications associated with gallstones, such as biliary obstruction, cholecystitis, or pancreatitis.

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:

Diarrhea.

You don't have to be overly concerned if you see this side effect unless it is severe, worsens, or continues to be a problem. Contact your veterinarian if this happens.

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

- Vomiting, poor appetite.
- ▶ Depression, low energy level.
- ▶ Yellowing of the skin, whites of the eyes, or gums (jaundice).

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: **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.

- Ursodiol works best when given with food.
- ▶ 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, wait to give the next dose when it is usually time to do so. Do not double-up doses or give an extra dose.

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?

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?

- ▶ Do not give at the same time as antacids containing aluminum (eg, Maalox®, Amphojel®, Alternagel®).
- ▶ Your veterinarian will need to do periodic examinations and blood tests on your animal while it is taking this medicine. Do not miss these important follow-up visits.
- ▶ 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:			