Ursodeoxycholic Acid, Ursodiol capsules or tablets

MEDICATION GUIDE

What is this medicine?

URSODIOL (ER soe dye ol) helps dissolve gallstones in patients who cannot have or who do not need gallbladder surgery. This medicine is also useful for certain liver diseases of adults, children and infants.

This medicine may be used for other purposes; ask your health care provider or pharmacist if you have questions.

How should I use this medicine?

Take this medicine by mouth with a glass of water. Follow the directions on the prescription label. Take your doses at regular intervals. Do not take your medicine more often than directed. Do not stop taking except on the advice of your doctor or health care professional.

Talk to your pediatrician regarding the use of this medicine in children. Special care may be needed.

Overdosage: If you think you have taken too much of this medicine contact a poison control center or emergency room at once.

NOTE: This medicine is only for you. Do not share this medicine with others.

What if I miss a dose?

If you miss a dose, take it as soon as you can. If it is almost time for your next dose, take only that dose. Do not take double or extra doses.

What should I tell my health care provider before I take this medicine?

They need to know if you have any of these conditions:

• Blocked bile duct or fistula
• Pancreatitis
• An unusual or allergic reaction to ursodiol, bile acids, other medicines, foods, dyes, or preservatives
• Pregnant or trying to get pregnant
• Breast-feeding

What may interact with this medicine?

• Antacids
• Cholestyramine
• Clofibrate, fenofibrate, or gemfibrozil
• Colesevelam
• Colestipol
• Female hormones, including estrogens or birth control pills

This list may not describe all possible interactions. Give your health care provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use. Also tell them if you smoke, drink alcohol, or use illegal drugs. Some items may interact with your medicine.

What side effects may I notice from receiving this medicine?

Side effects that you should report to your doctor or health care professional as soon as possible:

• Allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue
• Severe stomach area pain, especially toward your right side

Side effects that usually do not require medical attention (report to your doctor or health care professional if they continue or are bothersome):

• Constipation
• Gas
• Indigestion
• Nausea

This list may not describe all possible side effects. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
What should I watch for while using this medicine?

Visit your doctor or health care professional for regular checks on your progress. It may take months of therapy to get the right response. Your doctor or health care professional will schedule tests to see if your gallstones are dissolving or if your liver problem is improving. You may also need blood work done while you are taking this medicine to check that your liver is working properly. Report continued or worsened nausea, vomiting, or abdominal pain to your doctor.

Antacids may interfere with the absorption of this medicine. Take this medicine at least 1 hour before or 2 hours after an antacid dose.

Where should I keep my medicine?

Keep out of the reach of children.
Store at room temperature between 15 and 30 degrees C (59 and 86 degrees F). Keep container tightly closed. Throw away any unused medicine after the expiration date.

NOTE: This sheet is a summary. It may not cover all possible information. If you have questions about this medicine, talk to your doctor, pharmacist, or health care provider.