

Looking for PBC treatment with fewer pills?



Ask your doctor about
NEW URSO Forte™
for Primary Biliary Cirrhosis

NEW



Urso Forte™

(Ursodiol Tablets, USP) 500 mg

Introducing New URSO Forte™

What is URSO Forte™?

You may have heard the term “URSO” before. URSO is short for “ursodiol,” which is a naturally occurring bile acid. URSO Forte™ (pronounced er-so for-tay) is a new, larger dose ursodiol tablet that is used to treat Primary Biliary Cirrhosis (PBC). It is the same drug as URSO 250®, but it contains more ursodiol (500 mg vs 250 mg).

How may URSO Forte™ help make my treatment easier?

Because URSO Forte™ contains twice as much ursodiol as URSO 250®, you may be able to take half as many pills. For example, to reach the recommended daily dose of ursodiol, a PBC patient weighing approximately 160 lbs would need to take:

- **2 URSO Forte™ tablets per day,*** or
- 4 URSO 250® tablets per day,* or
- 4 Actigall® capsules per day

Actigall® and its generics are not approved by the Food and Drug Administration (FDA) for PBC treatment.

Important note: URSO Forte™ and URSO 250® are the only ursodiol products FDA-approved for the treatment of PBC. URSO Forte™ and URSO 250® are also the only ursodiol tablets available.

Studies have shown that ursodiol tablets¹:

- Reduce treatment failure and the need for liver transplant^{1,2}
- May slow down the progression of PBC, lengthening the time from diagnosis to the need for a liver transplant^{2,3}
- Reduce the frequency of esophageal varices (veins in the esophagus that enlarge and may bleed)^{3,4}
- Improve signs and symptoms of PBC with long-term treatment⁴
- Have few side effects and are well tolerated by most patients^{1,3}

*The recommended adult dosage for URSO Forte™ and URSO 250® in the treatment of PBC is 13 to 15 mg/kg/day in 2 to 4 divided doses with food.

URSO Forte™ and PBC treatment

What is PBC?

PBC is a disease that slowly destroys the ducts in the liver that drain bile. Bile is the liquid substance produced by the liver to carry away waste. If the bile ducts are damaged, bile and waste build up in the liver and in the blood. This causes inflammation and scarring of the liver, which, over a period of years, may lead to end-stage cirrhosis. But with early diagnosis and proper medications, most people with PBC will not reach the end stage of cirrhosis.

How does URSO Forte™ help treat PBC?

URSO Forte™ may help treat PBC in part by changing the makeup of the bile acid pool so that the circulating bile salts are less toxic. This decreases the harmful effects associated with high levels of bile acids and slows the progression of the disease. It may also reduce liver cell death.⁵

How can I get the best results from my treatment?

- **Seek early treatment.** Ursodiol products, such as URSO Forte™, have been shown to benefit people the most when treatment is started in the early stages of the disease.⁴
- **Take URSO Forte™ exactly as prescribed.**
- **Continue to take URSO Forte™ as long as your doctor prescribes it for you.** If you feel like you want to stop taking any of your medications, be sure to talk to your doctor about it. Your doctor may be able to adjust your therapy so it works better for you.
- **Be patient.** It may take several years for you to see the benefits of treatment.



What are other advantages of ursodiol tablets?

URSO Forte™ and URSO 250® are the only ursodiol tablets available. All other ursodiol products are capsules.

Specialists prefer ursodiol tablets.⁶

- 3 out of 4 hepatologists prescribe the lower-dose equivalent of URSO Forte™, URSO 250®, more than any other product in its class for PBC⁶

Most PBCers use ursodiol tablets.⁷

- 68% of people surveyed currently take URSO 250® or took URSO 250® before they stopped taking ursodiol⁷

More of the product is absorbed by the body.⁸

One study has shown that more of the active ingredient in ursodiol tablets is absorbed by the body when compared to ursodiol capsules. This means that more of the active ingredient is available for the liver to use to help slow the progression of PBC. Why does this happen? The body absorbs more ursodiol when it is taken as a tablet versus when it is taken as a capsule.⁸



Look for the tablet!

URSO Forte™ and URSO 250® are the only products of their class in a tablet form.



Remember!

If you are taking a generic or another brand-name ursodiol, you may not be getting the same benefits of URSO Forte™ and URSO 250®.

Treatment tips and information

Take URSO Forte™ as prescribed.

Be sure to follow your doctor's instructions about taking URSO Forte™. Dosing is based on each patient's needs. Keep using it according to your doctor's instructions even if you feel better.

What are the most common side effects?

In scientific studies, the most common side effects of URSO Forte™ were a general feeling of weakness, high blood pressure, chest pain, severe itching, swelling in the ankles, feet, and/or legs, nausea or upset stomach, and other disorders of the stomach and intestine. Less frequent events included diabetes, cyst and breast tumors, stomach pain, anorexia, inflammation of the esophagus, high creatinine levels, high blood glucose levels, low levels of certain white blood cells, peptic ulcer, and skin rash.

Who should not take URSO Forte™?

As a precaution, people who have had an allergic-type reaction to ursodiol, or to any of its ingredients, should not take URSO Forte™. Also, people with complications of advanced liver disease such as variceal bleeding, hepatic encephalopathy, ascites, and those who are in urgent need of a liver transplant should receive appropriate treatment before starting on URSO Forte™.¹

Are there any medications that I should avoid when taking URSO Forte™?

Though they may not harm you, there are certain medications that may reduce the efficacy of URSO Forte™. These include estrogens, birth control pills, and lipid-lowering drugs (for high cholesterol).

Also, if you take antacids with aluminum in them or bile acid-sequestering agents, be sure to take them 2 to 3 hours before taking URSO Forte™.¹

Be sure to ask your doctor if you have further questions about PBC or URSO Forte™.

Patient Information

URSO Forte™

(Ursodiol Tablets, USP) 500 mg

Read this information carefully before you begin taking URSO Forte™. This information does not take the place of talking with your doctor about your medical condition or your treatment. Whenever you get a refill for URSO Forte™, make sure to read the instructions that are given to you. They may contain updated information. If you have any questions about URSO Forte™, ask your doctor or pharmacist.

What is URSO Forte™?

URSO Forte™ is a medicine made from ursodiol and is used to treat Primary Biliary Cirrhosis (PBC).

Ursodiol is a naturally occurring bile acid. Bile acids are made in the liver and flow down the bile ducts to the intestine where they are needed to help digest the fats in the food we eat.

What are the ingredients of URSO Forte™?

Active ingredient: ursodiol

Inactive ingredients: microcrystalline cellulose, povidone, sodium starch glycolate, magnesium stearate, ethylcellulose, dibutyl sebacate, carnauba wax, hydroxypropyl methylcellulose, PEG 3350, PEG 8000, cetyl alcohol, sodium lauryl sulfate, and hydrogen peroxide.

Who should not use URSO Forte™?

Do not use URSO Forte™ if you are allergic to ursodiol or if you are allergic to any of its ingredients. Tell your doctor of any allergies you may have before taking URSO Forte™.

Also before taking URSO Forte™, tell your doctor if you have, or have had, any of the following:

- Variceal bleeding (eg, veins that enlarge and bleed)
- Hepatic encephalopathy (eg, nervous system damage due to liver failure)
- Ascites (eg, accumulation of fluid in the abdominal cavity)
- You are in need of a liver transplant

Do not take URSO Forte™ without first talking to your doctor if you are pregnant or breastfeeding.

How should I take URSO Forte™?

Take URSO Forte™ exactly as prescribed by your doctor. It is usually taken 2 to 4 times per day. Make sure to take each dose with food.

Missed doses should be taken as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue your regular dosing schedule. You should not take double doses.

What should I avoid while taking URSO Forte™?

Avoid taking over-the-counter antacids that contain aluminum. These products decrease the effectiveness of ursodiol.

What other drugs will affect URSO Forte™?

Before taking URSO Forte™, inform your doctor if you are taking any of the following drugs:

- Cholestyramine or colestipol, which can reduce the absorption of URSO Forte™
- Birth control pills, estrogens, clofibrate, or any other lipid-lowering drugs. These may increase the amount of cholesterol in your body and decrease the effects of URSO Forte™

Drugs other than those listed here may also interact with URSO Forte™. Talk to your doctor before taking any prescription or over-the-counter medicine.

What are the possible side effects of URSO Forte™?

If you experience any of the following serious side effects, stop taking URSO Forte™ and seek immediate medical attention:

- An allergic reaction (eg, difficulty breathing; closing of your throat; swelling of your lips, tongue, or face; hives)

If you experience any of the following less serious adverse reactions, continue with the medication as scheduled and speak with your doctor:

- Nausea or upset stomach
- High blood pressure
- Diarrhea
- Chest pain
- Headache
- Severe itching
- General feeling of weakness
- Swelling in your ankles, feet, or legs

Side effects other than those listed above may also occur. Talk to your doctor about any side effect that seems unusual.

How should I store URSO Forte™?

- Store at controlled room temperature, 20° to 25°C (68° to 77°F)
- Keep out of reach of children

General advice about prescriptions

Medicines are sometimes prescribed for conditions that are not mentioned in patient information brochures. Do not use URSO Forte™ for a condition for which it was not prescribed. Do not give URSO Forte™ to other people, even if they have the same symptoms you have.

For more information, you can also visit www.URSOForte.com, or call 1-800-472-2634.



Remember, there is a difference between URSO Forte™ and other ursodiol products. Ask your doctor if URSO Forte™ is right for you.

Axcan is committed to PBC patients.

Axcan Pharma™, the company that markets URSO Forte™ and URSO 250®, is dedicated to providing patients with the best possible care. As part of this commitment, Axcan continually supports scientific research on URSO Forte™ and URSO 250® in PBC and a variety of other liver diseases. Axcan also provides support through:

- ASSIST ProgramSM — **www.axcan.com**
- The PBCers Organization™ — **www.pbcers.org**
- American Liver Foundation (ALF) — **www.liverfoundation.org**

For more information, visit **www.URSOForte.com**.

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