

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

**PrURSO® / URSO DS®**

#### **Ursodiol tablets**

Read this carefully before you start taking **Urso and Urso DS** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Urso and Urso DS**.

#### **What is Urso and Urso DS used for?**

- URSO or URSO DS is used to manage cholestatic liver disease.

#### **How does Urso and Urso DS work?**

URSO and URSO DS contain ursodiol (ER-so-DYE-all), which is a naturally occurring bile acid found in small quantities in normal human bile.

Cholestatic liver disease is caused when the release and flow of bile through the bile ducts from your liver are reduced. By taking URSO or URSO DS the amount of ursodiol in the bile increases, changing the make-up of the bile and causing an increase in bile flow. Ursodiol also works by replacing toxic bile acids that can destroy liver tissue.

#### **What are the ingredients in Urso and Urso DS?**

Medicinal ingredients: ursodiol

Non-medicinal ingredients: carnauba wax, dibutyl sebacate, ethylcellulose aqueous (cetyl alcohol, ethylcellulose, hydrogen peroxide, sodium lauryl sulfate), hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, and sodium starch glycolate.

#### **Urso and Urso DS comes in the following dosage forms:**

Tablets; 250 mg and 500 mg

#### **Do not use Urso and Urso DS if you:**

- have an allergy to ursodiol or to any ingredient in the formulation.
- have blockage of bile flow due to widespread liver disease.
- have complete blockage of bile flow due to disease outside of the liver.

#### **To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Urso or Urso DS. Talk about any health conditions or problems you may have, including if you:**

- have taken URSO or URSO DS before and it was not well-tolerated or caused an allergy.
- have liver problems, or are in need of a liver transplant.
- have a partial blockage of bile flow due to disease outside of the liver.
- have variceal bleeding (bleeding from swollen veins, arteries, or lymph vessels).

- have ascites (swelling in the abdomen).
- are pregnant, plan to become pregnant, are breast-feeding or plan to breast-feed.
- need other medical treatment by another healthcare professional let him or her know that you are taking URSO or URSO DS.

**Other warnings you should know about:**

**Laboratory tests:** Your healthcare professional may do certain tests during your treatment. These include liver function tests and bilirubin levels every month for three months after start of treatment, and every six months thereafter.

**Bezoars in Patients with a Risk for Blockage in the Gut (intestine):** A bezoar is where material builds up in the stomach or gut, causing a blockage. This can cause symptoms such as nausea, vomiting, and pain in the belly area. Bezoars may cause a blockage that requires surgery. This very rare side effect happened in patients who were taking URSO and had medical conditions that caused stomach or gut blockage (such as previous gut surgery or Crohn’s disease).

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with Urso and Urso DS:**

- Medicines that reduce the amount of bile acids such as cholestyramine or colestipol
- Antacids that contain aluminum such as Roloids, Maalox, Mylanta, and many others.
- Cyclosporine
- Dapsone
- Nitrendipine

**How to take Urso and Urso DS:**

- Take URSO and URSO DS for the full duration of treatment, even if you begin to feel better.
- To break URSO DS scored tablet easily, place the tablet on a flat surface with the scored section on top. Hold the tablet with your thumbs placed close to the scored part of the tablet (groove). Then apply gentle pressure and snap the tablet segments apart (segments breaking incorrectly should not be used). The segments should be swallowed unchewed, with water.
- To prevent leakage of the active medicinal ingredient (ursodiol) from the cut tablets onto the surface of whole tablets and spreading the bitter taste, it is recommended that cut tablets be stored separately from whole tablets.
- This medication should only be used as instructed by your healthcare professional. Follow your healthcare professional’s instructions. Do not change the dose or stop the treatment without your healthcare professional’s advice.

**Usual dose:**

Your healthcare professional would have prescribed the amount of URSO or URSO DS you should take each day for your medical condition. URSO and URSO DS should be taken in 2 to 4 divided doses with food. It is easier to remember to take your medication if it is taken at the same time each day. Setting up a routine to take your medication helps this activity become a normal part of your day.

**Overdose:**

The most severe symptom of overdosage would likely be diarrhea.

If you think you, or a person you are caring for, have taken too much URSO or URSO DS, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you miss a dose, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the dose you missed and take your next regularly scheduled dose. Do not take a double dose.

**What are possible side effects from using Urso and Urso DS?**

These are not all the possible side effects you may have when taking Urso and Urso DS. If you experience any side effects not listed here, tell your healthcare professional.

Side effects include:

- Dizziness
- Headache
- Indigestion
- Itchiness
- Swelling of the extremities

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>COMMON</b>			
Anemia (decreased number of red blood cells): fatigue, loss of energy, looking pale, shortness of breath, weakness		✓	
Blood glucose increased		✓	
<b>RARE</b>			
Intestinal blockage or obstruction (blockage that stops or impairs passage of contents of intestines): cramping pain in abdomen that may begin suddenly, bloating, loss of appetite, pain that comes and goes but will then last, nausea and vomiting, constipation or diarrhea			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNKNOWN</b>			
Swelling beneath the skin and Swelling of the throat			✓
Palpitations: fast-beating, fluttering or pounding heart	✓		
Eosinophilia (increased numbers of certain white blood cells): abdominal pain, rash, weight loss, wheezing.		✓	
Allergic Reaction: difficulty swallowing or breathing, wheezing, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat.			✓
Neutropenia (decreased number of certain white blood cells): infections, fatigue, fever, aches, pains and flu-like symptoms		✓	
Interstitial lung disease: shortness of breath at rest, dry cough			✓
Thrombocytopenia (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness		✓	
Skin Reactions: Severe inflammation and peeling of the skin, Skin redness and Papular skin lesions (small solid bumps on skin), or Sensitivity to Light			✓
New or worsening Jaundice: yellow appearance of the skin and white portion of the eyes			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

URSO and URSO DS tablets should be stored at room temperature at 15°C to 30°C in a closed container.

Half-tablets can be stored for up to 28 days in the original container at 15°C to 30 °C.

Keep out of reach and sight of children.

### **If you want more information about Urso and Urso DS:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website [www.allergan.ca](http://www.allergan.ca), or by contacting the sponsor 1-800-668 6424.

This leaflet was prepared by Aptalis Pharma Canada ULC.

URSO is a registered trademark of Aptalis Pharma Canada ULC, an Allergan affiliate, used under license by Allergan Inc.

Last Revised FEB 23, 2023