

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Ursosan?

Ursosan contains active ursodeoxycholic acid. Ursosan may be used to treat liver diseases such as primary biliary cirrhosis (PBC), primary sclerosing cholangitis (PSC), and cystic fibrosis (CF)-related cholestasis. For more information, see Section [1. Why am I using Ursosan?](#) in the full CMI.

2. What should I know before I use Ursosan?

Do not use if you have ever had an allergic reaction to ursodeoxycholic acid or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Ursosan?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Ursosan and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Ursosan?

The dose for Ursosan is determined by your body weight. Your doctor will tell you how much Ursosan you should take.

More instructions can be found in Section [4. How do I use Ursosan?](#) in the full CMI.

5. What should I know while using Ursosan?

Things you should do	<ul style="list-style-type: none"> Remind any doctor, dentist or pharmacist you visit that you are using Ursosan. If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. If you are about to have any blood tests, tell your doctor that you are taking this medicine. If you become pregnant while taking this medicine, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none"> Do not stop taking Ursosan or change the dosage without checking with your doctor. Do not take Ursosan to treat any other complaints unless your doctor tells you to. Do not give your medicine to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none"> Ursosan does not cause any negative effect on driving ability and operating machinery.
Looking after your medicine	<ul style="list-style-type: none"> Keep Ursosan in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using Ursosan?](#) in the full CMI.

6. Are there any side effects?

Ursodeoxycholic acid is generally well tolerated with few side effects. The common side effect is diarrhoea. Allergic reactions have been reported in some patients. Other adverse reactions reported include increased cholestasis, nausea, vomiting and sleep disturbance. The serious side effects include severe right-sided upper abdominal pain and severe worsening (decompensation) of liver cirrhosis.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Ursosan®

Active ingredient(s): *ursodeoxycholic acid*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Ursosan.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Ursosan.

Where to find information in this leaflet:

- [1. Why am I using Ursosan?](#)
- [2. What should I know before I use Ursosan?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Ursosan?](#)
- [5. What should I know while using Ursosan?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Ursosan?

Ursosan contains ursodeoxycholic acid.

Ursodeoxycholic acid is a bile acid, which may have a protective effect on the liver by reducing the absorption of other potentially toxic bile salts.

Ursosan may be used to treat liver diseases such as primary biliary cirrhosis (PBC), primary sclerosing cholangitis (PSC), and cystic fibrosis (CF)-related cholestasis.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why it has been prescribed for you.

Ursosan is only available with a doctor's prescription.

Ursosan is not addictive.

2. What should I know before I use Ursosan?

Warnings

Do not use Ursosan if:

- you are allergic to any medicine containing ursodeoxycholic acid, bile acids or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have a bile duct or gall bladder that is swollen, painful or blocked.
- you have certain types of cholesterol stones or bile pigment stones

- your doctor advises you that you will have your gall bladder removed.
- Do not take it after the expiry date printed on the pack.

Check with your doctor if you:

- take any medicines for any other condition.
- have allergies to any other medicines, foods, preservatives or dyes.
- kidneys that do not work properly
- a deficiency in a certain step of metabolism (sulfation)
- calcified gallstones
- frequent cramp-like pains in the upper abdomen (biliary colic).
- have a gall bladder that cannot be seen on X-ray.
- have a gall bladder which is not able to contract properly.

If you are not sure whether you or your child should start taking this medicine, talk to your doctor.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor can discuss with you the risks and benefits involved.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Ursosan may increase the effect of some medicines, including:

- medicines used to lower high levels of cholesterol in the blood, such as rosuvastatin, atorvastatin, fluvastatin, simvastatin, pitavastatin or pravastatin.

Ursosan may decrease the effects / absorption of some medicines, including:

- nitrendipine (used to treat high blood pressure) and other medicines which are metabolised in the same way.

- medicines used to suppress the immune system, such as ciclosporin;
- antibiotics used to prevent certain infections, such as ciprofloxacin or dapsone.

Medicines that may reduce the effect of Ursosan

include:

- medicines used to lower high levels of cholesterol in the blood, such as colestyramine or colestipol; an absorbent, such as charcoal;
- medicines such as antacids containing aluminium hydroxide and/or smectite, which are used for indigestion.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Ursosan.

4. How do I use Ursosan?

How much to take

- The dose for Ursosan is determined by your body weight.
- Your doctor will tell you how much Ursosan you should take.
- The standard adult dose, depending on your weight and the condition being treated, is between two to nine capsules per day.
- Ask your doctor or pharmacist if you are unsure of the correct dose for you.
- Swallow Ursosan whole with a full glass of water, because the content of the capsules is bitter.
- If you take the wrong dose, Ursosan may not work as well, and your problem may not improve.

When to take Ursosan

- Ursosan should be taken regularly and at about the same time(s) each day. Taking it at the same time(s) each day will have the best effect. It will also help you to remember when to take it.
- If you need to take cholesterol lowering medicines or an antacid, take it at least two hours before or two hours after the dose of Ursosan.
- Ursosan capsules should be swallowed whole with a full glass of water because the content is bitter.
- Take Ursosan capsules regularly.

How long to take Ursosan

- Continue taking the capsules for as long as your doctor tells you to.
- Ursosan helps to control your condition but does not cure it. It is important to keep taking the medicine even if you feel well. You may need to take Ursosan for many months for it to work.
- **If you are unsure whether you should stop taking Ursosan, talk to your doctor or pharmacist.**

If you forget to take Ursosan

Ursosan should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for hints.

If you take too much Ursosan

If you think that you have used too much Ursosan, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include diarrhoea. If you suffer from diarrhoea, make sure you drink enough liquids to replace the fluid and electrolyte balance.

5. What should I know while using Ursosan?

Things you should do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Ursosan. Likewise, tell any other doctors, dentists and pharmacists who are treating you that you are taking this medicine.

If you are going to have surgery, tell the surgeon and anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you are about to have any blood tests, tell your doctor that you are taking Ursosan.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may perform liver function tests. During the first three months of taking Ursosan, your doctor should monitor your liver function every four weeks. After the first three months of taking this medicine, your doctor should monitor your liver function every three months.

See your doctor if you feel that your condition is not improving or it is getting worse.

Call your doctor straight away if you:

- become pregnant while taking this medicine.

Remind any doctor, dentist you visit that you are using Ursosan.

Things you should not do

- **Do not give your medicine to anyone else, even if they have the same condition as you.** This medicine is only intended for the person it has been prescribed for.
- **Do not take Ursosan to treat any other complaints unless your doctor tells you to.**
- **Do not stop taking Ursosan or change the dosage without checking with your doctor.**

Driving or using machines

Ursosan does not cause any negative effect on driving ability and operating machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Keep your capsules in the pack until it is time to take them. If you take the capsules out of the pack they may not keep well.

Keep Ursosan in a cool dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • Diarrhoea • Itching/pruritus • Urticaria (nettle rash) • Allergic reactions • Nausea/vomiting • Sleep disturbance • Pain in the stomach area or in the upper right part of the belly, under the ribs 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Severe right-sided upper abdominal pain. 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice this serious side effect (During treatment of PBC).</p>
<ul style="list-style-type: none"> • Serious allergic reaction (swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing) • Severe diarrhoea. 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice these serious side effects.</p>
<ul style="list-style-type: none"> • Severe worsening (decompensation) of liver cirrhosis. 	<p>Stop taking Ursosan immediately if you notice this serious side effect (During treatment of PBC).</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Ursosan contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">• Ursodeoxycholic acid.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• maize starch• pregelatinised maize starch• colloidal anhydrous silica• magnesium stearate• gelatin• titanium dioxide• purified water.
Potential allergens	Ursosan does not contain lactose, sucrose, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What Ursosan looks like

Ursosan is available in blister packs of 100 capsules.

The capsules are white in colour.

Australian Registration Number: AUST R 218444

Who distributes Ursosan

Boucher & Muir Pty Ltd

Level 9, 76 Berry Street

North Sydney NSW 2060

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