

Ursosan®

Capsules 250 mg

ursodeoxycholic acid

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start taking Ursosan.

This leaflet answers some common questions about Ursosan. It does not contain all the available information. The most up-to-date Consumer Medicine Information can be downloaded from www.ebs.tga.gov.au (Australia) or www.medsafe.govt.nz (New Zealand).

Reading this leaflet does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Ursosan against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may want to read it again.

What Ursosan is used for

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.

Before you take Ursosan

Ursosan is not suitable for everyone.

When you must not take it

Do not take 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
- 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.

If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking Ursosan, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- 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.

Tell your doctor if you are pregnant or intend to become pregnant.

Ursosan is not generally recommended for use during pregnancy. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breast-feeding or planning to breast-feed.

It is not known whether the active ingredient in Ursosan passes into breast milk.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Ursosan.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from

your pharmacy, supermarket or health food shop.

Tell any healthcare professional who is prescribing a new medicine for you that you are taking Ursosan.

Some medicines and Ursosan may interfere with each other. These include:

- colestyramine, colestipol or statins (e.g. rosuvastatin, atorvastatin, fluvastatin, simvastatin acid, pitavastatin and pravastatin) medicines used to lower high levels of cholesterol in the blood
- adsorbents such as charcoal
- antacids or medicines used for indigestion that contain aluminium hydroxide and/or smectite (aluminium oxide)
- ciclosporine, a medicine used to suppress the immune system
- ciprofloxacin, an antibiotic used to treat certain infections
- nitrendipine (used to treat high blood pressure), dapsone (an anti-infective) and other medicines which are metabolised in a similar way (by cytochrome P450 3A4)
- oestrogens (female hormones)
- the oral contraceptive pill
- clofibrate, a medicine used to reduce high blood fat levels.

The above medicines may be affected by Ursosan, or may affect how well it works. You may need different amounts of Ursosan, or take it at different times, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Ursosan.

How to take Ursosan

Read the label carefully and follow all directions given to you by your doctor and pharmacist.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

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.

They will tell you exactly how much to take. This depends on your condition and whether or not you are taking any other medicines.

If you take the wrong dose, Ursosan may not work as well and your problem may not improve.

Swallow Ursosan whole with a full glass of water, because the content of the capsules is bitter.

When to take it

Take it 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.

How long to take it

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 it

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

Do not try to make up for missed doses by taking more than one dose at a time.

This may increase the chance of getting an unwanted side effect.

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

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.

While you are taking Ursosan

Things you must 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 become pregnant while taking this medicine, tell your doctor immediately.

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 is getting worse.

Things you must 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.

In case of overdose

If you take too much

Immediately telephone your doctor, or the Poisons Information Centre (Australia - telephone 13 11 26; New Zealand - telephone 0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Ursosan.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Ursosan.

Like all medicines, Ursosan may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor immediately if you notice any of the following:

- 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 abdomen, under the ribs.

During treatment of primary biliary cirrhosis (PBC), tell your doctor immediately if you notice any of the following:

- severe right-sided upper abdominal pain.

During treatment of primary biliary cirrhosis (PBC), stop taking Ursosan if you have the following:

- severe worsening (decompensation) of liver tissue damage.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- serious allergic reaction (swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing)
- severe diarrhoea.

These are very serious side effects; you may need urgent medical attention or hospitalisation.

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

Other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking Ursosan

Storage

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.

Do not store it or any other medicine in the bathroom, near a sink, or on a window sill. Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it and any other medicine where children cannot reach it.

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

Do not keep Ursosan past its expiry date.

Disposal

Return any unused medicine and any medicine past its expiry date (as shown on the labelling) to your pharmacy.

Product description

What it looks like

Ursosan is available in blister packs of 100 capsules. The capsules are white in colour.

Ingredients

Active ingredient:

- ursodeoxycholic acid.

Inactive ingredients:

- maize starch
- pregelatinised maize starch
- colloidal anhydrous silica
- magnesium stearate
- gelatin
- titanium dioxide
- purified water.

Ursosan does not contain lactose, sucrose, tartrazine or any other azo dyes.

Sponsor details

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