

# APO-Ursodeoxycholic Acid Capsules

## 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 APO-Ursodeoxycholic Acid Capsules?

APO-Ursodeoxycholic Acid Capsules contains the active ingredient ursodeoxycholic acid. APO-Ursodeoxycholic Acid Capsules is used to treat chronic cholestatic liver diseases. For more information, see Section [1. Why am I using APO-Ursodeoxycholic Acid Capsules?](#) in the full CMI.

### 2. What should I know before I use APO-Ursodeoxycholic Acid Capsules?

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 APO-Ursodeoxycholic Acid Capsules?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with APO-Ursodeoxycholic Acid Capsules 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 APO-Ursodeoxycholic Acid Capsules?

Take APO-Ursodeoxycholic Acid Capsules, or give to your child, as directed by your doctor or pharmacist. This may differ from the information contained in this leaflet.

More instructions can be found in Section [4. How do I use APO-Ursodeoxycholic Acid Capsules?](#) in the full CMI.

### 5. What should I know while using APO-Ursodeoxycholic Acid Capsules?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist, or pharmacist you visit that you or your child are using APO-Ursodeoxycholic Acid Capsules.</li><li>If you or your child are going to have surgery, tell the surgeon or anaesthetist that you or your child are taking this medicine.</li><li>If you or your child are about to have any blood tests, tell your doctor that you or your child are taking this medicine.</li><li>If you become pregnant while taking this medicine, tell your doctor immediately.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not stop taking APO-Ursodeoxycholic Acid Capsules or change the dosage without checking with your, or your child's, doctor.</li><li>Do not take APO-Ursodeoxycholic Acid Capsules to treat any other complaints unless your doctor tells you or your child to.</li><li>Do not give this medicine to anyone else, even if they have the same condition as you or your child.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Be careful when driving or operating machinery until you know how this medicine affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Keep APO-Ursodeoxycholic Acid Capsules in a cool dry place where the temperature stays below 25°C.</li></ul>

For more information, see Section [5. What should I know while using APO-Ursodeoxycholic Acid Capsules?](#) 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.

# APO-Ursodeoxycholic Acid Capsules

Active ingredient(s): *ursodeoxycholic acid*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-Ursodeoxycholic Acid Capsules. **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 APO-Ursodeoxycholic Acid Capsules.**

### Where to find information in this leaflet:

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

## 1. Why am I using APO-Ursodeoxycholic Acid Capsules?

**APO-Ursodeoxycholic Acid Capsules contains the active ingredient ursodeoxycholic acid.** APO-Ursodeoxycholic Acid Capsules is a bile acid, which may have a protective effect on the liver by reducing the absorption of other potentially toxic bile salts.

**APO-Ursodeoxycholic Acid Capsules is used to treat liver diseases such as primary biliary cholangitis (PBC), primary sclerosing cholangitis (PSC), and cystic fibrosis (CF)-related cholestasis.**

However, your doctor may prescribe this medicine for another use.

If you or your child wants more information, ask your doctor.

Ask your doctor if you or your child have any questions about why this medicine has been prescribed for you or your child.

APO-Ursodeoxycholic Acid Capsules is not addictive.

## 2. What should I know before I use APO-Ursodeoxycholic Acid Capsules?

### Warnings

**Do not use APO-Ursodeoxycholic Acid Capsules if:**

- you or your child are allergic to ursodeoxycholic acid, or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing, difficulty breathing or tightness in chest; swelling of the face, lips, tongue, throat

or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

**If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**

Always check the ingredients to make sure you can use this medicine.

- you or your child has a bile duct or gall bladder that is swollen, painful or blocked.
- the packaging is torn or shows signs of tampering.
- the capsules look to be deteriorating in any way.
- the expiry date (EXP) printed on the pack has passed, as it may not work as well.

### Check with your doctor if you or your child:

- take any medicines for any other condition;
- have allergies to any other medicines, foods, preservatives or dyes;
- have kidneys that do not work properly;
- have a gall bladder that cannot be seen on X-ray;
- have calcified gallstones;
- have a gall bladder which is not able to contract properly;
- suffer from frequent cramp-like pains in the upper abdomen (biliary colic);
- plan to have surgery or an anaesthetic;
- take or plan to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

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

Tell 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.

### Use in children

This medicine should not be used in children.

## 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.

APO-Ursodeoxycholic Acid Capsules 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.

APO-Ursodeoxycholic Acid Capsules 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 dapson.

Medicines that may reduce the effect of APO-Ursodeoxycholic Acid Capsules 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 APO-Ursodeoxycholic Acid Capsules.**

## 4. How do I use APO-Ursodeoxycholic Acid Capsules?

### How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

The dose for ursodeoxycholic acid is determined by your body weight. Your doctor should tell you how much ursodeoxycholic acid you or your child should take.

**Adults** - the usual dose, depending on your weight, is as follows:

For PBC and chronic cholestatic liver diseases other than CF and PSC - two to seven capsules per day.

For CF-related cholestasis - three to nine capsules per day.

For PSC - one to nine capsules per day.

**Children** - the usual dose depends on your child's weight and will be advised by your doctor.

Ursodeoxycholic acid should be taken in divided doses, two to three times a day.

For PBC patients - during the first 3 months of treatment, you or your child should take ursodeoxycholic acid capsules in two to three divided doses. With improvement of liver function tests, the daily dose may be taken in one single dose in the evening.

Follow the instructions provided and use APO-Ursodeoxycholic Acid Capsules until your doctor tells you to stop.

### When to take APO-Ursodeoxycholic Acid Capsules

- Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.
- If you or your child needs to take a cholesterol lowering medicine or an antacid, take it at least 2 hours before or 2 hours after the dose of ursodeoxycholic acid.
- It does not matter if you take it before, with or after food.
- Ursodeoxycholic acid should be taken in divided doses, two to three times a day.
- For PBC patients - during the first 3 months of treatment, you or your child should take ursodeoxycholic acid capsules in two to three divided doses. With improvement of liver function tests, the daily dose may be taken in one single dose in the evening.

### How to take APO-Ursodeoxycholic Acid Capsules

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

Ursodeoxycholic acid capsules should be swallowed whole with a full glass of water because the content is bitter. Take ursodeoxycholic acid capsules regularly.

### How long to take APO-Ursodeoxycholic Acid Capsules

Continue taking your medicine for as long as your doctor tells you.

Ursodeoxycholic acid helps to control you or your child's condition, but does not cure it. It is important to keep taking the medicine even if you or your child feels well.

If you are unsure whether you or your child should stop taking ursodeoxycholic acid, talk to your doctor or pharmacist.

You or your child may need to take ursodeoxycholic acid for many months for it to work.

Make sure you have enough to last over weekends and holidays.

## If you forget to use APO-Ursodeoxycholic Acid Capsules

APO-Ursodeoxycholic Acid Capsules should be used regularly at the same time each day. If you miss your dose at the usual time, if it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

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

**This may increase the chance of you experiencing side effects.**

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

## If you use too much APO-Ursodeoxycholic Acid Capsules

If you think that you have used too much APO-Ursodeoxycholic Acid Capsules, 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 or your child suffers from diarrhoea, make sure you or your child drink enough liquids to replace the fluid and electrolyte balance.

## 5. What should I know while using APO-Ursodeoxycholic Acid Capsules?

### Things you should do

**Call your doctor straight away if you or your child:**

- are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- are about to have any blood tests
- are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Go to your doctor regularly for a check-up.

Your doctor may do tests to assess you or your child's liver function.

During the first three months of taking ursodeoxycholic acid, your doctor should monitor you or your child's liver function every 4 weeks. After the first three months of taking this medicine, your doctor should monitor you or your child's liver function every 3 months.

See your doctor if you (or your child) feels that you or your child's condition is not improving or is getting worse.

Remind any doctor, dentist or pharmacist you visit that you or your child are using APO-Ursodeoxycholic Acid Capsules.

### Things you should not do

- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not take your medicine to treat any other condition unless your doctor tells you to.
- Do not stop taking your medicine, or change the dosage, without first checking with your doctor.

### Driving or using machines

Be careful when driving or operating machinery until you know how this medicine affects you.

### Drinking alcohol

Tell your doctor if you drink alcohol.

### Looking after your medicine

**Keep your medicine in a cool dry place where the temperature will stay below 25°C.**

Keep your medicine in its original packaging until it is time to take it. If you take your medicine out of its original packaging it may not keep well.

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; for example, do not store it:

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

**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"><li>• Diarrhoea</li></ul>	<b>Speak to your</b>

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

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• Severe right-sided upper abdominal pain.</li> </ul>	<p><b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you or your child notice this serious side effect (especially during the treatment of PBC).</b></p>
<ul style="list-style-type: none"> <li>• Severe worsening (decompensation) of liver cirrhosis.</li> </ul>	<p><b>Stop taking ursodeoxycholic acid immediately if you notice this serious side effect (especially during treatment of PBC).</b></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](http://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 APO-Ursodeoxycholic Acid Capsules contains

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"> <li>• Ursodeoxycholic acid</li> </ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• Maize starch</li> <li>• Silicon dioxide</li> <li>• Magnesium stearate</li> <li>• Titanium dioxide</li> <li>• Gelatin</li> </ul>
<b>Potential allergens</b>	May contain trace amounts of phenylalanine and sulfites.

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

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

### What APO-Ursodeoxycholic Acid Capsules looks like

APO-Ursodeoxycholic Acid Capsules 250 mg is a white hard gelatine capsule. The content - white or almost white powder. (Aust R 276339).

APO-Ursodeoxycholic Acid Capsules are available in blister pack of 100 capsules.

### Who distributes APO-Ursodeoxycholic Acid Capsules

Arrotex Pharmaceuticals Pty Ltd

15 – 17 Chapel Street

Cremorne VIC 3121

[www.arrotex.com.au](http://www.arrotex.com.au)

This leaflet was prepared in March 2025.