

Ursodox GH

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 Ursodox GH?

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

2. What should I know before I use Ursodox GH?

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 Ursodox GH?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Ursodox GH 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 Ursodox GH?

- Take Ursodox GH, or give Ursodox GH 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 Ursodox GH?](#) in the full CMI.

5. What should I know while using Ursodox GH?

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

For more information, see Section [5. What should I know while using Ursodox GH?](#) 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.

Ursodox GH

Active ingredient: *ursodeoxycholic acid*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Ursodox GH. **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 Ursodox GH.**

Where to find information in this leaflet:

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

1. Why am I using Ursodox GH?

Ursodox GH contains the active ingredient ursodeoxycholic acid. Ursodox GH is a bile acid, which may have a protective effect on the liver by reducing the absorption of other potentially toxic bile salts.

Ursodox GH 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 has any questions about why this medicine has been prescribed for you or your child.

Ursodox GH is not addictive.

2. What should I know before I use Ursodox GH?

Do not use Ursodox GH if:

- you or your child are allergic to ursodeoxycholic acid, 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 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).

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.

Ursodox GH may increase the effects of some medicines, including:

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

Ursodox GH may decrease the effects of some medicines, including:

- medicines used to treat high blood pressure, such as nitrendipine.

Ursodox GH may decrease the absorption of some medicines, including:

- 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 Ursodox GH include (if you need take a preparation containing one of below substances, it must be taken at least 2 hours before or after Ursodox GH):

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

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

4. How do I use Ursodox GH?

How much to take

- The usual dosage for you or your child depends on the weight and medical conditions of you or your child and will be advised by your doctor.
- Follow the instructions provided and use Ursodox GH until your doctor tells you to stop.
- **If you or your child is unsure of how much of the medicine should be taken, ask your doctor or pharmacist.**
- **If you or your child has any questions about the prescribed dose, ask your doctor or pharmacist.**

When to take Ursodox GH

- Take Ursodox GH capsules at about the same time each day.
Taking it at the same time each day will have the best effect. It will also help you or your child to 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 Ursodox GH.

How to take Ursodox GH

- Ursodox GH capsules should be swallowed whole with a full glass of water because the content is bitter.

How long to take Ursodox GH

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

If you forget to use Ursodox GH

Ursodox GH should be used regularly at the same time each day. If you or your child miss a dose at the usual time, take the required dose as soon as you or your child remembers, and then go back to taking it as you or your child would normally.

If it is almost time for your next dose, skip the dose you or your child missed and take the next dose as you or your child would normally.

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

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

If you or your child has trouble remembering to take, or give, the medicine, ask your pharmacist for some hints.

If you use too much Ursodox GH

If you think that you or your child have used too much Ursodox GH, 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 drinks enough liquids to replace the fluid and electrolyte balance.

5. What should I know while using Ursodox GH?

Things you should do

If you or your child is about to be started on any new medicine, remind your doctor and pharmacist that you or your child is taking Ursodox GH.

If you or your child is going to have surgery, tell the surgeon or anaesthetist that you or your child is taking this medicine.

If you or your child is about to have any blood tests, tell your doctor that you or your child is taking this medicine.

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

During the first three months of taking Ursodox GH, 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.

Call your doctor straight away if you or your child:

- become pregnant while taking this medicine.

Remind any doctor, dentist or pharmacist you visit that you or your child are using Ursodox GH.

Things you should not do

- Do not take Ursodox GH to treat any other complaints unless your doctor tells you or your child to.

- Do not give this medicine to anyone else, even if they have the same condition as you or your child.
- Do not stop taking Ursodox GH or change the dosage without checking with your doctor or your child's doctor.

Driving or using machines

Ursodox GH 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

- Store below 25°C.
- Keep Ursodox GH capsules in the blister pack until it is time to take them.

Follow the instructions on 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.

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 or your child notice this serious side effect during the treatment of PBC.</p>
<ul style="list-style-type: none"> • Severe worsening (decompensation) of liver cirrhosis. 	<p>Stop taking Ursodox GH 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 Ursodox GH contains

Active ingredient (main ingredient)	Ursodeoxycholic acid
Other ingredients (inactive ingredients)	Maize starch Silica colloidal anhydrous Magnesium stearate <u>Capsule Shell:</u> Titanium dioxide Gelatin Yellow iron oxide* Capsugel Ink 10A1 Black (PI 109522)**

*Ursodox GH 250 mg capsule

**Ursodox GH 500 mg capsule

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

What Ursodox GH looks like

Ursodox GH 250 mg capsules are hard gelatin size 0 capsules with a yellow body and cap (AUST R 232480).

Ursodox GH 500 mg capsules are hard gelatin size 00 capsules with a white body and cap, imprinted with "500" on body in black ink (AUST R 400951).

Who distributes Ursodox GH capsules

Generic Health Pty Ltd

Suite 2, Level 2

19-23 Prospect Street

Box Hill, VIC, 3128

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🌐 www.generichealth.com.au

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