

URSOFALK®

ursodeoxycholic acid

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 URSOFALK?

URSOFALK contains the active ingredient ursodeoxycholic acid. URSOFALK is used to treat chronic cholestatic liver diseases.

For more information, see Section [1. Why am I using URSOFALK?](#) in the full CMI.

2. What should I know before I use URSOFALK?

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 URSOFALK?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with URSOFALK 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 URSOFALK?

- Take URSOFALK, 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 URSOFALK?](#) in the full CMI.

5. What should I know while using URSOFALK

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 URSOFALK.● 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 URSOFALK or change the dosage without checking with your, or your child's, doctor.

<p>Things you should do</p>	<ul style="list-style-type: none"> ● Remind any doctor, dentist, or pharmacist you visit that you or your child are using URSOFALK. ● 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.
	<ul style="list-style-type: none"> ● Do not take URSOFALK 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.

<p>Things you should do</p>	<ul style="list-style-type: none"> ● Remind any doctor, dentist, or pharmacist you visit that you or your child are using URSOFALK. ● 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.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● URSOFALK does not cause any negative effect on driving ability and operating machinery.
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> ● Keep URSOFALK 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 URSOFALK?](#) 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.

URSOFALK

Active ingredient: *ursodeoxycholic acid*

Consumer Medicine Information (CMI)

This leaflet provides important information about using URSOFALK. **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 URSOFALK.**

Where to find information in this leaflet:

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

1. Why am I using URSOFALK?

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

URSOFALK 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.

URSOFALK is not addictive.

2. What should I know before I use URSOFALK?

Warnings

Do not use URSOFALK 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, tablets or suspension look to be deteriorating in any way.
- the expiry date (EXP) printed on the pack has passed, as it may not work as well.
- do not use URSOFALK suspension after 4 months of opening the bottle.

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);
- is on a controlled sodium diet (for patients taking URSOFALK suspension).

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

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.

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.

URSOFALK 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.

URSOFALK 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 dapsonsone.

Medicines that may reduce the effect of URSOFALK 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 URSOFALK.

4. How do I use URSOFALK?

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 URSOFALK 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.**

Adults

–

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

Two
to
seven
capsules
cholestatic
liver
diseases
other
than
G₂
G₁lets
and
PSC
two
to
seven
5
mL
spoonfuls
of

Adults

–

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

the suspension per day

Free of related cholestasis or 1 $\frac{1}{2}$ to 4 $\frac{1}{2}$ tablets or three to nine

Adults

–

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

5 mL spoonfuls of the suspension per day

Five (5) RSC nine capsules or $\frac{1}{2}$ to 4 $\frac{1}{2}$ tablets

Adults

–

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

or

one
to
nine
5
mL
spoonfuls
of
the
suspension
per
day.

Children

-

**the
usual
dose,
depending**

Adults

–

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

on your child's weight, is as follows:

For patients under 34 kg (5 mL patients who are unable to swallow suspension)

Adults

–

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

URSOFALK
per day
capsules
or
tablets,
URSOFALK
suspension
should
be
used.

When to take URSOFALK

- Take URSOFALK 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 URSOFALK.

How to take URSOFALK

- URSOFALK capsules or tablets should be swallowed whole with a full glass of water because the content is bitter.
- For URSOFALK suspension, shake the bottle well before use and accurately measure the dose with a medicine measure.
- Shaking the bottle and using a medicine measure will make sure that you or your child gets the correct dose. You can buy a medicine measure from your pharmacist.
- Take URSOFALK capsules, tablets or suspension regularly.

How long to take URSOFALK

- Continue taking the medicine for as long as your doctor tells you or your child to.
- URSOFALK 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 URSOFALK, talk to your doctor or pharmacist.
- You or your child may need to take URSOFALK for many months for it to work.

If you or your child forget to use URSOFALK

URSOFALK 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 or your child uses too much URSOFALK

If you think that you or your child have used too much URSOFALK, 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 URSOFALK?

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 URSOFALK.

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 URSOFALK, 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:

- become pregnant while taking this medicine.

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

Things you should not do

- Do not take URSOFALK 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 URSOFALK or change the dosage without checking with your doctor or your child's doctor.

Driving or using machines

URSOFALK 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 URSOFALK capsules, tablets or suspension in the blister pack/bottle until it is time to take them.

If you or your child take/takes URSOFALK out of the pack/bottle they will not keep well.

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

Store URSOFALK capsules, tablets or suspension 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 or your child have any of these less serious side effects and they worry you or your child.</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 (especially during the treatment of PBC).</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • Severe worsening (decompensation) of liver cirrhosis. 	<p>Stop taking URSOFALK immediately if you notice this serious side effect (especially 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 URSOFALK Capsule contains

Active ingredient (main ingredient)	Ursodeoxycholic acid 250 mg
Other ingredients (inactive ingredients)	maize starch colloidal anhydrous silica magnesium stearate gelatin titanium dioxide sodium lauryl sulfate.

What URSOFALK Tablet contains

Active ingredient (main ingredient)	Ursodeoxycholic acid 500 mg
Other ingredients (inactive ingredients)	magnesium stearate polysorbate 80 povidone microcrystalline cellulose colloidal anhydrous silica crospovidone purified talc

Active ingredient (main ingredient)	Ursodeoxycholic acid 500 mg
	hypromellose macrogol 6000.

What URSOFALK Suspension contains

Active ingredient (main ingredient)	Ursodeoxycholic acid 250 mg / 5 mL
Other ingredients (inactive ingredients)	benzoic acid purified water xylitol glycerol Avicel RC-591 propylene glycol sodium citrate dihydrate sodium cyclamate citric acid sodium chloride lemon flavour (PHL 134488)

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

What URSOFALK looks like

URSOFALK Capsules are white, opaque, hard gelatin capsules. A box contains blister packs of 60 or 100 capsules.

URSOFALK Tablets are white, oblong tablets equipped with a breaking notch. A box contains blister of 50 or 100 tablets. Starter packs of 25 tablets are also available.

Not all pack sizes are currently marketed in Australia.

URSOFALK Suspension is a white liquid containing small air bubbles, and has a lemon flavour (PHL 134488). It comes in bottles of 250 mL.

Australian Registration Numbers:

URSOFALK Capsules AUST R 66042

URSOFALK Suspension AUST R 75484

URSOFALK Tablets AUST R 262732

Who distributes URSOFALK

Dr Falk Pharma Australia Pty Ltd

9 Help Street

Chatswood, NSW 2067

Australia

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