Ursofalk®
Ursodeoxycholic Acid

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Ursofalk. It does not contain all of the available information. 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 your taking Ursofalk against the benefits they expect it will have for you or your child.

If you have any concerns about taking Ursofalk, ask your doctor or pharmacist. Keep this leaflet. You or your child may want to read it again.

What Ursofalk is used for

Ursofalk 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.

Ursofalk may be used to treat liver diseases such as primary biliary cirrhosis (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.

Ursofalk is not addictive.

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

Before you or your child takes Ursofalk

Ursofalk is not suitable for everyone.

When you or your child must not take Ursofalk

Do not take Ursofalk if:

• you or your child is allergic to ursodeoxycholic acid or any other ingredients listed at the end of this leaflet
• 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

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

Before you or your child starts to take it

Tell your doctor if you or your child:

• 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).

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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

If you or your child has not told your doctor any of the above, tell him/her before you or your child starts taking Ursofalk.

Taking other medicines

Tell your doctor or pharmacist if you or your child is taking any other medicines, including any that you or your child gets without a prescription from your pharmacy, supermarket or health food shop.

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

• cholestyramine, or colestoipol, medicines used to lower high levels of cholesterol in the blood
• an absorbent such as charcoal
• antacids or medicines used for indigestion that contains aluminium hydroxide and/or smectite (aluminium oxide)
• cyclosporine, medicine used to suppress the immune system
• ciprofloxacin and dapsone, an antibiotic used to prevent certain infections
• nitrindipine (used to treat high blood pressure) and other medicines which are metabolised in a similar way.

These medicines may be affected by Ursofalk or may affect how well Ursofalk works. You or your child may need different amounts of Ursofalk or at different times, or you or your child needs to take different medicines.

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

How to take Ursofalk

Take Ursofalk, or give Ursofalk to your child, as directed by your doctor or pharmacist. They may differ from the information contained in this leaflet.

If you or your child does not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

How much to take

The dose for Ursofalk is determined by your body weight. Your doctor should tell you how much Ursofalk 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 or one to 3½ tablets (or two to seven 5 mL spoonfuls of the suspension) per day.

For CF-related cholestasis -
• Three to nine capsules or 1½ to 4½ tablets (or three to nine 5 mL spoonfuls of the suspension) per day.

For PSC -
• one to nine capsules or ½ to 4½ tablets (or one to nine 5 mL spoonfuls of the suspension) per day.

Children – the usual dose, depending on your child’s weight, is as follows:
• ½ to 1½; spoonfuls (5 mL per spoonful) of the suspension per day.

Administration:
Ursofalk 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 Ursofalk capsules, tablets or suspension 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.

If you or your child is unsure of how much of the medicine you or your child should take, ask your doctor or pharmacist.

If you or your child has any questions about the prescribed dose, you or your child should ask your doctor or pharmacist.

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.

When to take it

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 long to take it

Continue taking the medicine for as long as your doctor tells you or your child to. Ursofalk 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 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 forgets to take it
Take it 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 that 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 takes too much
Immediately telephone your doctor, or the
Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and
Emergency at the nearest hospital, if you
think that you or anyone else may have
taken too much Ursofalk. Do this even if
there are no signs of discomfort or
poisoning.
You or your child may need urgent medical
attention.
Keep telephone numbers for these places
handy.
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.

While you or your child is taking
Ursofalk

Things you or your child must 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.
Tell any other doctors, dentists, and
pharmacists who treat you or your child
that you or your child is taking this
medicine.
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 become pregnant while taking this
medicine, tell your doctor immediately.
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.
Your doctor may do tests to assess you or
your child’s liver function.
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.
See your doctor if you or your child feels
that you or your child’s condition is not
improving or is getting worse.

Things you or your child must not do
Do not take Ursofalk to treat any other
complaints unless your doctor tells you or
your child to.
Do not give your or your child’s 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.

Side effects
Tell your doctor or pharmacist as soon as
possible if you or your child does not feel
well while taking Ursofalk.
Like all medicines, Ursofalk may
occasionally cause side effects in some
people. Sometimes they are serious, most of
the time they are not. You or your child may
need medical attention if you or your child
gets some of the side effects.
Do not be alarmed by the following list
of side effects. You or your child may not
experience any of them.
Ask your doctor or pharmacist to answer
any questions you or your child may have.
Side effects are normally mild, but if you or
your child experiences the following effects, stop
taking Ursofalk and tell your doctor
immediately:
• 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
During the treatment of primary biliary
cirrhosis, tell your doctor immediately if
you or your child notices any of the
following:
• Severe right-sided upper abdominal pain
During treatment of primary biliary
cirrhosis, stop taking Ursofalk if you have the
following:
• Severe worsening (decompensation) of
liver cirrhosis
Tell your doctor or pharmacist if you or
your child experiences any other
undesirable effects, particularly if they are
severe or persistent.

After using Ursofalk

Storage
Keep the Ursofalk capsules, tablets or
suspension in the blister pack/bottle until
it is time to take them.
If you or your child takes Ursofalk out of the
pack/bottle they will not keep well.
Keep Ursofalk capsules, tablets or
suspension in a cool, dark and dry place
where the temperature stays below 25°C.
Do not store Ursofalk or any other
medicine in the bathroom or near a sink.
Do not leave it on a window sill or in the
car.
Heat and dampness can destroy some
medicines.
Keep Ursofalk and all other medicines
where children cannot reach them.
A locked cupboard at least one and a half
metres above the ground is a good place to
store medicines.

Disposal
If your doctor tells you or your child to
stop taking this medicine or the expiry
date has passed, ask your pharmacist what
to do with any medicine that is left over.

Product description
What Ursofalk looks like
Ursofalk Capsules are white, opaque, hard
gelatin capsules. A box contains blister packs
of 100 capsules.
Ursofalk Tablets are white, oblong tablets
equipped with a breaking notch. A box
contains blister of 50 or 100 tablets. Not all pack
sizes are currently marketed in
Australia.
Ursofalk Suspension is a white liquid
containing small air bubbles, and has a
lemon flavour (Giovaund 87017). It comes in
bottles of 250 mL.

Ingredients
The active ingredient in Ursofalk is
ursodeoxycholic acid.
Each Ursofalk Capsule contains 250 mg of
ursodeoxycholic acid. These capsules also
contain maize starch, colloidal anhydrous silica,
magnesium stearate, gelatin, titanium
dioxide and sodium lauryl sulfate.
Each Ursofalk Tablet contains 500 mg
ursodeoxycholic acid. These tablets also
contain maize starch, colloidal anhydrous silica,
crospovidone, talc, hypromellose and magrocol
6000.
Each 5 mL of the Ursofalk Suspension
contains 250 mg of ursodeoxycholic acid.
The suspension also contains benzenoic acid,
purified water, xylitol, glycerol, 
mcrocrystalline cellulose, colloidal anhydrous silica,
sodium sulfate, propylene glycol, sodium citrate,
sodium cyclamate, anhydrous citric acid,
sodium chloride and 87017 lemon flavour.

Australian Registration Number:
Ursofalk Capsules AUST R 66042
Ursofalk Suspension AUST R 75484
Ursofalk Tablets AUST R 262732

Distributor
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