

Package leaflet: Information for the user

Ursofalk® 250mg hard capsules

Ursodeoxycholic acid

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet, see section 4.

What is in this leaflet:

1. What Ursofalk capsules are and what they are used for
2. What you need to know before you take Ursofalk capsules
3. How to take Ursofalk capsules
4. Possible side effects
5. How to store Ursofalk capsules
6. Contents of the pack and further information

1. What Ursofalk 250mg hard capsules are and what they are used for

Ursodeoxycholic acid (UDCA), the active substance in Ursofalk capsules, is a naturally occurring bile acid. Small amounts are found in human bile.

Ursofalk capsules are used:

- for the treatment of a condition where the bile ducts in the liver become damaged; leading to a build-up of bile. This may cause scarring of the liver. The liver should not be so damaged that it is not functioning properly. This condition is called primary biliary cirrhosis (PBC).
- to dissolve gallstones caused by excess cholesterol in the gall bladder where the gallstones are not visible on a plain x-ray (gallstones that are visible will not dissolve) and not more than 15 mm in diameter. The gall bladder should still be working despite the gallstone(s).
- for liver disease associated with a condition called cystic fibrosis in children aged 6 to 18 years.

2. What you need to know before you take Ursofalk 250mg hard capsules

Do NOT take Ursofalk capsules if

- you are, or have been told you are, allergic (hypersensitive) to bile acids like UDCA or to any of the other ingredients of Ursofalk capsules (listed in section 6).
- your gall bladder does not work properly.
- your doctor has said you have calcified gallstones (they are visible on an x-ray).
- you have an acute inflammation of the gall bladder or biliary tract.
- you have a blockage of the common bile duct or cystic duct (obstruction of the biliary tract).
- you have frequent cramp-like pains in the upper abdomen (biliary colic).
- you are a child with biliary atresia and have poor bile flow, even after surgery.

Please ask your doctor about any of the conditions mentioned above. You should also ask if you have previously had any of these conditions or if you are unsure whether you have any of them.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ursofalk capsules.

Your doctor should test your liver function regularly every 4 weeks for the first 3 months of treatment. After this time, it should be monitored at 3 month intervals.

When used in the treatment of PBC, in rare cases the symptoms may worsen at the beginning of treatment. If this happens, please speak to your doctor about reducing your initial dose.

When used to dissolve gallstones, your doctor should arrange for a scan of your gall bladder after the first 6-10 months of treatment.

Please inform your doctor immediately if you have diarrhoea, as this may require a reduction in the dose or discontinuation of treatment.

Other medicines and Ursofalk capsules

The effects of these medicines may be altered:

A **reduction in the effects** of the following medicines is possible when taking Ursofalk capsules:

- colestyramine, colestipol (to lower blood lipids) or antacids containing aluminium hydroxide or smectite (aluminium oxide). If you must take medication that contains any of these ingredients, it must be taken at least two hours before or after Ursofalk.
- ciprofloxacin and dapsons (antibiotics), nitrendipine (used to treat high blood pressure). It may be necessary for your doctor to alter the dose of these medicines.

A **change in the effects** of the following medicines is possible when taking Ursofalk capsules:

- ciclosporin (to reduce the activity of the immune system). If you are being treated with ciclosporin, your doctor should check the amount of ciclosporin in your blood. Your doctor will adjust its dose, if necessary.
- rosuvastatin (for high cholesterol and related conditions)

Please inform your doctor, if you are taking any blood cholesterol lowering agents such as clofibrate or medicines that contain oestrogen (estrogen); especially if you are taking Ursofalk capsules for the dissolution of gallstones, as they may stimulate the formation of gallstones.

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, even if they are medicines obtainable without a prescription. Treatment with Ursofalk capsules may still be allowed. Your doctor will know what is right for you.

Pregnancy, breastfeeding and fertility: If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy: You should not take Ursofalk during pregnancy unless your doctor thinks it is absolutely necessary.

Women of child-bearing potential: Even if you are not pregnant, you should still discuss this possibility with your doctor. Before starting treatment with Ursofalk, your doctor will

check that you are not pregnant and review your contraceptive method to make sure it is appropriate.

Breastfeeding: Tell your doctor if you are breastfeeding or about to start breastfeeding.

Driving and using machines:

No particular precautions are necessary.

3. How to take Ursofalk 250mg capsules

Always take Ursofalk capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Ursofalk suspension is available if a lower dose is needed or you cannot swallow capsules.

For primary biliary cirrhosis (chronic inflammation of the bile ducts)

Dosage

During the first 3 months of treatment, you should take Ursofalk capsules in the morning, at midday and in the evening. As liver function values improve, the total daily dose may be taken once a day in the evening.

Body weight BW (kg)	Daily dose (mg/kg BW)	Ursofalk 250mg hard capsules			
		First 3 months			Subsequently
		Morning	Midday	Evening	Evening (once daily)
47 – 62	12 – 16	1	1	1	3
63 – 78	13 – 16	1	1	2	4
79 – 93	13 – 16	1	2	2	5
94 – 109	14 - 16	2	2	2	6
over 110		2	2	3	7

How to take Ursofalk capsules

Swallow the capsules whole with a drink of water or other liquid. Take your medicine regularly.

Duration of treatment

Ursofalk capsules may be continued indefinitely in cases of PBC.

To dissolve cholesterol gallstones

Dosage

Approximately 10mg per kg body weight (BW) daily, as follows:

50 - 62kg 2 capsules daily

63 - 85kg 3 capsules daily

86 - 120kg 4 capsules daily

How to take Ursofalk capsules

Swallow the capsules whole with a drink of water or other liquid. Take the capsules in the evening at bedtime. Take your medicine regularly.

Duration of treatment

It generally takes 6-24 months to dissolve gallstones. If there is no reduction in the size of the gallstones after 12 months, therapy should be stopped.

Every 6 months, your doctor should check whether the treatment is working. At each of these follow-up examinations, it should be checked whether a build-up of calcium causing hardening of the stones has occurred since the last time. If this happens, your doctor will stop the treatment.

Both Indications:**Use in elderly:**

There is no evidence to suggest that any alteration in the adult dose is needed but your doctor will take your age and health into consideration.

Use in children and adolescents:

The administration of Ursofalk is based on body weight and the condition being treated.

Use in children (6 to 18 years) for treatment of liver disease associated with cystic fibrosis**Dosage**

The recommended daily dose is 20mg per kg body weight, divided in 2-3 doses. Your doctor may want to increase the dose further to 30mg per kg body weight daily if necessary.

Body weight BW [kg]	Daily dose [mg/kg BW]	Ursofalk 250mg hard capsules		
		Morning	Midday	Evening
20 – 29	17-25	1	--	1
30 – 39	19-25	1	1	1
40 – 49	20-25	1	1	2
50 – 59	21-25	1	2	2
60 – 69	22-25	2	2	2
70 – 79	22-25	2	2	3
80 – 89	22-25	2	3	3
90 – 99	23-25	3	3	3
100 – 109	23-25	3	3	4
>110		3	4	4

How to take Ursofalk capsules

Take the capsules two to three times per day, as advised. Take the capsules regularly.

Duration of treatment

Treatment can be continued long term (up to 12 years) in children with cystic fibrosis associated hepatobiliary disorders.

If you feel that the effect of Ursofalk capsules is too strong or too weak, please talk to your doctor or pharmacist.

If you take more Ursofalk capsules than you should:

Diarrhoea may occur as a result of overdose. Please inform your doctor immediately if you have persistent diarrhoea. If you do suffer from diarrhoea, make sure you drink enough liquids to replace your fluid and electrolyte balance.

If you forget to take Ursofalk capsules:

Do not take more capsules the next time, but just continue the treatment with the prescribed dose.

If you stop taking Ursofalk capsules:

Always talk to your doctor before you decide to interrupt treatment with Ursofalk capsules or decide to stop your treatment early.

4. Possible side effects

Like all medicines, Ursofalk capsules can cause side effects, although not everybody gets them.

Common side effects (occurring in less than 1 in 10 but more than 1 in 100 patients):

- soft, loose stools or diarrhoea.

Very rare side effects (occurring in less than 1 in 10,000 patients):

- during the treatment of PBC: severe right-sided upper abdominal pain, severe worsening of liver scarring - this partially eases after treatment is stopped
- hardening of gallstones due to build-up of calcium. There are no additional symptoms of this but it will show up in tests.
- nettle rash (urticaria)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly as follows:

Ireland:

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie

UK

Yellow Card Scheme
Tel: Freephone 0800 100 3352
Website: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ursofalk 250mg capsules

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the carton and the container after "Expiry date". The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and further information

What Ursofalk 250mg hard capsules contain

The active substance is UDCA. One capsule contains 250mg UDCA.

The other ingredients are (capsule contents): silica, colloidal anhydrous, magnesium stearate, maize starch. (capsule shell): gelatin, titanium dioxide (E171), sodium lauryl sulphate

What Ursofalk 250mg hard capsules look like and contents of the pack

Ursofalk capsules are white, opaque hard gelatin capsules containing a white powder or granules.

Ursofalk capsules are available in packs of 60 or 100 capsules.

Not all packs may be marketed.

Marketing Authorisation Holder:

Ireland

Dr Falk Pharma GmbH

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79108 Freiburg

Germany

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UK

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Cores End Road

Bourne End, Buckinghamshire

SL8 5AS, UK

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Other sources of information:

Further information, help, advice and details of local support groups can be found at:

The PBC Foundation

2 York Place

Edinburgh

Scotland

EH1 3EP

Telephone: +44 (0) 131 556 6811

The British Liver Trust

2 Southampton Road

Ringwood

England

BH24 1HY

Telephone: +44 (0) 1425 481320