Package leaflet: Information for the user

Ursofalk® 500 mg film-coated tablets

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 possible side effects not listed in this leaflet, see section 4.

What is in this leaflet:

1. What Ursofalk 500 mg film-coated tablets are and what they are used for

Ursofalk tablets contain the active substance ursodeoxycholic acid (UDCA). Small amounts of UDCA are found in human bile.

Ursofalk tablets are used:
- for the treatment of primary biliary cholangitis (PBC) 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 (cirrhosis of the liver). The liver should not be so damaged that it is not functioning properly.
- to dissolve cholesterol gallstones. These stones must not be visible on a plain X-ray (radiolucent) and be no larger than 15 mm in diameter because they will not dissolve with UDCA. The gall bladder must 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 500 mg film-coated tablets

Do NOT take Ursofalk tablets if:
- you are, or have been told you are, allergic (hypersensitive) to bile acids like UDCA or to any of the other ingredients of this medicine (listed in section 6).
- 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 upper abdomen pain (biliary colic).
- your doctor has said you have calcified gallstones (they are visible on an x-ray).
- your gall bladder does not work properly.
- you are a child with biliary atresia and have poor bile flow, even after surgery.

Please ask your doctor about 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 tablets.

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 talk to your doctor immediately if you have diarrhoea, as this may require a reduction in the dose or discontinuation of the treatment with Ursofalk tablets.

Other medicines and Ursofalk tablets

The effects of these medicines may be altered:
A **reduction in the effects** of the following medicines is possible when taking Ursofalk tablets:
- 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 tablets.
- ciprofloxacin, dapsone (antibiotics), nitrendipine (used to treat high blood pressure) and other medicines which are metabolised in a similar way. 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 tablets:
- 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).

If you are taking Ursofalk tablets for the dissolution of gallstones, please inform your doctor in case you are taking any medicines that contain oestrogenic hormones or blood cholesterol lowering agents such as clofibrate. These medicines stimulate the formation of gallstones, which is a counter-effect to the treatment with Ursofalk.

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breast feeding, 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 breast-feeding or about to start breastfeeding.

Driving and using machines:
No particular precautions are necessary.

3. How to take Ursofalk 500 mg film-coated tablets

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

For the treatment of primary biliary cholangitis **(inflammation of the bile ducts)**
Dosage
During the first 3 months of treatment, you should take Ursofalk tablets in divided doses during the day. As liver function tests improve, the total daily dose may be taken once a day in the evening.

Body weight BW (kg)	Daily dose (mg/kg BW)	Ursofalk 500mg Film-coated Tablets			
		First 3 months		**Subsequently**	
		Morning	Midday	Evening	Evening (once daily)
47 – 62	12 – 16	½	½	½	1½
63 – 78	13 – 16	½	½	1	2
79 – 93	13 – 16	½	1	1	2½
94 – 109	14 – 16	1	1	1	3
over 110		1	1	1 ½	3½

How to take Ursofalk tablets
The tablet can be divided into equal doses. Swallow the tablets with a drink of water or other liquid. Do not crush or chew the tablets. Take the tablets regularly.

Duration of treatment
Ursofalk tablets can be continued indefinitely in cases of PBC.

To dissolve cholesterol gallstones
Dosage
Approximately 10 mg per kg body weight (BW) daily, as follows:

up to 60 kg	1 tablet
61 – 80 kg	1½ tablets
81 – 100 kg	2 tablets
over 100 kg	2½ tablets

How to take Ursofalk tablets
The tablet can be divided into equal doses. Swallow the tablets with a drink of water or other liquid.
Do not crush or chew the tablets. Take the tablets in the evening at bedtime. Take the tablets 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 calcification of the stones has occurred since the last time. If this is the case, your doctor will stop the treatment.

Both indications:
Ursofalk capsules or Ursofalk suspension are available if you weigh less than 47 kg or cannot swallow tablets.

Use in elderly:
There is no evidence to suggest that any alteration in the adult dose is needed but the relevant precautions should be taken into account.

Use in children and adolescents:
There are no age limits to the use of Ursofalk tablets. The administration of Ursofalk tablets is based on body weight and the medical condition.

Use in children (6 to 18 years) for treatment of liver disease associated with cystic fibrosis
Dosage
The recommended daily dose is 20 mg 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 500mg Film-coated Tablets**		
		Morning	**Midday**	**Evening**
20 – 29	17-25	½	-	½
30 – 39	19-25	½	½	½
40 – 49	20-25	½	½	1
50 – 59	21-25	½	1	1
60 – 69	22-25	1	1	1
70 – 79	22-25	1	1	1½
80 – 89	22-25	1	1½	1½
90 – 99	23-25	1½	1½	1½
100 – 109	23-25	1½	1½	2
>110		1½	2	2

How to take Ursofalk tablets
The tablet can be divided into equal doses. Swallow the tablets with a drink of water or other liquid. Do not crush or chew the tablets. Take the tablets 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 500 mg film-coated tablets is too strong or too weak, please talk to your doctor or pharmacist.

If you take more Ursofalk tablets 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 salt balance.

If you forget to take Ursofalk tablets
Do not take more tablets the next time, but just continue the treatment with the prescribed dose.

If you stop taking Ursofalk tablets:
Always speak to your doctor before you decide to interrupt treatment with Ursofalk tablets or decide to stop your treatment early.

4. Possible side effects

Like all medicines, Ursofalk tablets can cause side effects, although not everybody gets them.
Common: may affect up to 1 in 10 people
– soft, loose stools or diarrhoea

Very rare: may affect up to 1 in 10 000 people
– during the treatment of primary biliary cholangitis: severe right-sided upper abdominal pain, severe worsening of liver cirrhosis which partially eases after treatment is discontinued
– 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)

Not known: frequency cannot be estimated from the available data
− itching
− feeling sick, vomiting

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 via HPRA Pharmacovigilance, Website: www.hpra.ie.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Ursofalk 500 mg film-coated tablets

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 after EXP. The expiry date refers to the last day of that month.
This medicine 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 protect the environment.

6. Contents of the pack and other information

What Ursofalk tablets contain:
The active substance is ursodeoxycholic acid (UDCA). Each film-coated tablet contains 500 mg UDCA.
The other ingredients are:
Tablet core: magnesium stearate, polysorbate 80, povidone K 25, microcrystalline cellulose, colloidal anhydrous silica, crospovidone
(Type A), talc. Coating: talc, hypromellose and macrogol 6000.

What Ursofalk 500 mg film-coated tablets look like and contents of the pack
Ursofalk 500 mg film-coated tablets are white, oval, biconvex and scored on both sides. The tablet may be divided into half.
Ursofalk 500 mg film-coated tablets are available in packs of 100.
Not all packs may be marketed.

Manufactured by:
Dr. Falk Pharma GmbH Leinenweberstrasse 5 , 79108 Freiburg , Germany

Product procured from within the EU, repackaged and distributed by the PPA Holder:
PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

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