



**Package leaflet: Information for the user**  
**Ursodeoxycholic acid 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 possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What Ursodeoxycholic acid is and what it is used for
2. What you need to know before you take Ursodeoxycholic acid
3. How to take Ursodeoxycholic acid
4. Possible side effects
5. How to store Ursodeoxycholic acid
6. Contents of the pack and other information

**1. What Ursodeoxycholic acid is and what it is used for**

Ursodeoxycholic acid contains the active substance ursodeoxycholic acid.

Ursodeoxycholic acid is a chemical present naturally in the body and it helps to control the amount of cholesterol in the blood.

**Ursodeoxycholic acid is used:**

- to dissolve gallstones caused by excess cholesterol in the gall bladder (in patients for whom surgery is not an option), 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 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 cholangitis.
- to treat children and adolescents, aged 6 years to less than 18 years, who have liver problems associated with cystic fibrosis.

**2. What you need to know before you take Ursodeoxycholic acid**

**Do not take Ursodeoxycholic acid:**

- if you are allergic to ursodeoxycholic acid or any of the other ingredients of this medicine (listed in section 6);
- if you have acute inflammation of the gall bladder or biliary tract;
- if you have an obstruction of the biliary tract (blockage of the common bile duct or a cystic duct);
- if you suffer from frequent cramp-like pains in the upper abdomen (biliary colic);
- if you have gallstones caused by a build-up of calcium that are visible on an X-ray;
- if your gall bladder does not work properly;

Children with a condition where the bile ducts have not developed correctly (biliary atresia), who have had an operation (portoenterostomy) to treat this which has been unsuccessful or who have not had recovery of good bile flow, should not take ursodeoxycholic acid.

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.

**Warning and precautions**

Talk to your doctor or pharmacist before taking ursodeoxycholic acid.

Ursodeoxycholic acid must be used under medical supervision.

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 every 3 months.

Inform your doctor immediately if you have diarrhoea as this may require a reduction in the dose or stopping the treatment.

**Other medicines and Ursodeoxycholic acid**

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

A **reduction in the effects** of the following medicines is possible when taking ursodeoxycholic acid:

- colestyramine, colestipol (to lower blood lipids) or

antacids (to relieve indigestion or heartburn) containing aluminium hydroxide or smectite (aluminium oxide).

If you must take medicines that contain any of these ingredients, you should take these at least two hours before or after ursodeoxycholic acid.

- ciprofloxacin and dapsone (antibiotics), nitrendipine (used to treat high blood pressure). It may be necessary for your doctor to change the dose of these medicines.
- charcoal (used to treat indigestion and poisoning).

An **increase in the effects** of the following medicines is possible when taking ursodeoxycholic acid:

- 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.

Inform your doctor if you are taking any blood cholesterol lowering medicines such as clofibrate or medicines that contain oestrogen (hormone replacement therapy or the contraceptive pill), especially if you are taking ursodeoxycholic acid for the dissolution of gallstones, as they may stimulate the formation of gallstones.

**Pregnancy, breast-feeding 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.

**Fertility**

Use a reliable method of contraception – non-hormonal contraceptives (barrier methods) or low-oestrogen oral contraceptives are recommended. If you are taking this medicine for dissolution of gallstones, only use non-hormonal contraceptives, as hormonal oral contraceptives may stimulate the formation of gallstones.

**Pregnancy**

You should not take this medicine during pregnancy unless your doctor thinks it is absolutely necessary. Use of ursodeoxycholic acid during the first three months of pregnancy may affect the foetus.

Check that you are not pregnant before taking this medicine.

**Breast-feeding**

Do not take this medicine if you are breast-feeding as the active ingredient in this medicine may pass into breast milk. If treatment with ursodeoxycholic acid is necessary, then stop breast-feeding.

**Driving and using machines**

No particular precautions are necessary.

**Information on sodium content**

This medicine contains less than 1 mmol sodium (23 mg) per capsule, i.e. is essentially 'sodium-free'.

**3. How to take Ursodeoxycholic acid**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

The daily dose below serves as an example of how you can take the capsules.

**Dosage**

**Use in patients with damage to liver tissue by impaired bile flow (Primary Biliary cholangitis)**

Your doctor will determine your dose depending on your body weight. During the first 3 months of treatment, you should take 3-7 capsules in divided doses throughout the day. As the liver function improves, the total daily dose can be taken once, in the evening.

Primary Biliary cholangitis Stage I-III				
Daily dose (total number of capsules)	First 3 months (how many capsules to take throughout the day)			Subsequently  Evening (once daily)
	Morning	Afternoon	Evening	
3 capsules	1	1	1	3
4 capsules	1	1	2	4
5 capsules	1	2	2	5
6 capsules	2	2	2	6
7 capsules	2	2	3	7

Primary Biliary cholangitis Stage IV		
Daily dose (total number of capsules)	How many capsules to take throughout the day	
	Morning	Evening
2 capsules	1	1
3 capsules	1	2

Dimension - 180 x 420 mm

Front Side

**ARTWORK DETAIL LABEL**

<b>Product</b>	<b>Ursodeoxycholic acid 250 mg Hard Capsules</b>				
<b>Buyer/Country</b>	SPUK	<b>Component</b>	PACK INSERT		
<b>Dimension</b>	180 x 420 mm			<b>Pack</b>	----
<b>New Item Code</b>	1047127	<b>Old Item Code</b>	1041999		
<b>Colour Shades</b>	██████ BLACK			<b>No. of Colours</b>	1
<b>Change Control No.</b>	PC-TSG/2022/046 - Record Number: 333148			<b>Artwork Version</b>	8.0
<b>Design/Style</b>	Front & Back Side printing. To be supplied in the unfolded size.				
<b>Substrate</b>	60 GSM Paper.				
<b>Special Instructions</b>	PRINTING CLARITY TO BE CLEAR AND SHARP.				
<b>Autocartonator Requirements</b>	Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.				
<b>Caution to the printer:</b> Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. <b>DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.</b>					

If you do not experience any problems at this dose (after blood tests and/or according to an evaluation), your doctor will prescribe you a higher dose (dosage in accordance with the treatment of stage I-III).

**Duration of treatment**

Your doctor will determine the duration of treatment. It may be necessary to get your blood checked regularly by the laboratory. Ursodeoxycholic acid may be continued indefinitely in cases of primary biliary cholangitis.

**Note:**

In patients with primary biliary cholangitis, the symptoms may worsen at the start of treatment, for example the itching may increase. This only occurs in rare cases. If this happens, therapy can be continued with a lower daily dose of ursodeoxycholic acid. Each week, your doctor will then gradually increase the daily dose, until you reach the required dose.

**Use in patients with gallstones**

The recommended dose is approximately 10 mg of ursodeoxycholic acid per kg body weight per day, taken as follows:

Patients with gallstones	
Body Weight (kg)	How many capsules to take in the evening before bedtime
Up to 60 kg	2 capsules
61-80 kg	3 capsules
81-100 kg	4 capsules
More than 100 kg	5 capsules

**Duration of treatment**

It generally takes 6-24 months to dissolve gallstones. The duration of your treatment depends on the size of the existing gallstones at the beginning of the treatment. Even if your symptoms have disappeared, you should continue with the treatment. Stopping treatment may result in the extension of the total treatment time. After the gallstones have been dissolved, the treatment should be continued for 3-4 months. 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.

If you feel that the effect of ursodeoxycholic acid is too strong or too weak, talk to your doctor or pharmacist.

**Use in children with cystic fibrosis aged 6 years to less than 18 years**

The recommended dose is 20 mg per kg body weight per day in 2-3 divided doses, with a further increase to 30 mg per kg body weight per day if necessary.

There are no age limits to the use of ursodeoxycholic acid. The administration of ursodeoxycholic acid is based on body weight and the medical condition. If the patient cannot swallow capsules or has a bodyweight below 47 kg, other pharmaceutical forms (suspension) are available.

**If you take more Ursodeoxycholic acid than you should**

If you or anyone else take too many capsules, seek immediate medical attention.

**If you forget to take Ursodeoxycholic acid**

Do not take a double dose to make up for a forgotten dose.

**If you stop taking Ursodeoxycholic acid**

Always speak to your doctor before you decide to interrupt treatment with ursodeoxycholic acid or to stop your treatment early.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Contact your doctor immediately if you experience any of the following symptoms after taking Ursodeoxycholic acid:**

**Common side effects** (may affect up to 1 in 10 people):

- soft, loose stools or diarrhoea. Inform your doctor immediately if you have persistent diarrhoea, as this may require a reduction in the dose of your medicine. If you do suffer from diarrhoea, make sure you drink enough liquids to replace your fluid and salt balance.

Diarrhoea may also occur as a result of overdose.

**Very rare side effects** (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 scarring - this partially improves 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).

**Not known** (frequency cannot be estimated from the available data)

- being sick (vomiting), feeling sick (nausea).
- in patients with cirrhosis, aggravation of pruritus (itching) at the beginning of the treatment cannot be completely ruled out.
- in patients with stage IV primary biliary cholangitis, there may be an increase in the concentration of certain enzymes (alkaline phosphates, gamma-glutamyltransferase) and bilirubin.

**Reporting of side effects**

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via Yellow Card Scheme at agency's website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Ursodeoxycholic acid**

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

**Expiry date**

Do not use this medicine after the expiry date which is stated on the blister label and carton after 'EXP'. The expiry date refers to the last day of that month.

**Storage**

This medicinal product does not require any special storage conditions.

**Disposal**

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 Ursodeoxycholic acid contains**

- The active substance is ursodeoxycholic acid. Each capsule contains 250 mg ursodeoxycholic acid.
- The other ingredients are:
  - **Capsule contents:** povidone (Kollidon K-30) (E1201), sodium lauryl sulphate (E487), maize starch, magnesium stearate (E572).
  - **Capsule shell:** gelatin (E441), titanium dioxide (E 171).

**What Ursodeoxycholic acid looks like and contents of the pack**

Ursodeoxycholic acid are white hard gelatin capsules (size '0') containing a white to off white powder.

The capsules are available in colourless PVC film with aluminium blister foil packed in cardboard cartons.

Ursodeoxycholic acid is available in packs of 20, 28, 30, 50, 56, 60, 100 and 120 capsules.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder**

**Strides Pharma UK Ltd.**

Unit 4, The Metro Centre,

Dwight Road, Watford,

WD 189SS

United Kingdom

**Manufacturer**

**Strides Pharma UK Ltd.**

Unit 4, The Metro Centre,

Dwight Road, Watford,

WD 189SS

United Kingdom

**This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**

Ireland: Ursodeoxycholic acid Strides 250 mg Hard Capsules

Netherlands: Ursodeoxycholzuur Strides 250 mg harde capsules

United Kingdom

(Northern-Ireland): Ursodeoxycholic acid 250 mg Hard Capsules

**This leaflet was last revised in 04/2023.**



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Dimension - 180 x 420 mm

Back Side

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