

Package leaflet: Information for the user

Ursodeoxycholic acid Strides 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ursodeoxycholic acid Strides is and what it is used for
2. What you need to know before you take Ursodeoxycholic acid Strides
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1. What Ursodeoxycholic acid Strides is and what it is used for

Ursodeoxycholic acid Strides 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 Strides 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 cirrhosis.
- for paediatric population: to treat children, 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 Strides

Do not take Ursodeoxycholic acid Strides:

- if you are allergic to bile acids like ursodeoxycholic acid or any of the other ingredients of this medicine (listed in section 6);
- if your gall bladder does not work properly;
- if you have gallstones that are visible on an x-ray;
- 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 hardening of the gallstones caused by a build-up of calcium;

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, pharmacist or nurse before taking Ursodeoxycholic acid Strides.

Ursodeoxycholic acid Strides 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 at 3 month intervals.

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 Strides

Tell your doctor, pharmacist or nurse 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 Strides 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 Strides:

- colestyramine, charcoal, colestipol (to lower blood lipids) or antacids 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 Strides.
- ciprofloxacin and dapson (antibiotics), nitrendipine (used to treat high blood pressure). It may be necessary for your doctor to change the dose of these medicines.

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

- 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 agents such as clofibrate or medicines that contain oestrogen (estrogen), especially if you are taking Ursodeoxycholic acid Strides 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.

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

Check that you are not pregnant before taking this medicine.

- 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.

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 Strides is necessary, then stop breast-feeding.

Driving and using machines

No particular precautions are necessary.

3. How to take Ursodeoxycholic acid Strides

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 Cirrhosis)

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 Cirrhosis Stage I-III				
Daily dose (total number of capsules)	First 3 months (how many capsules to take throughout the day)			Subsequently
	Morning	Afternoon	Evening	Evening (once daily)
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 Cirrhosis 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

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 Strides may be continued indefinitely in cases of primary biliary cirrhosis.

Note:

In patients with primary biliary cirrhosis, 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 Strides. 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 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 Strides is too strong or too weak, talk to your doctor or pharmacist.

Use in children

Children with cystic fibrosis aged 6 years to less than 18 years: 20 mg/kg/day in 2-3 divided doses, with a further increase to 30 mg/kg/day if necessary

There are no age limits to the use of Ursodeoxycholic acid Strides 250mg hard capsules. The administration of Ursodeoxycholic acid Strides 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 Strides than you should

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

If you forget to take Ursodeoxycholic acid Strides

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

If you stop taking Ursodeoxycholic acid Strides

Always speak to your doctor before you decide to interrupt treatment with Ursodeoxycholic acid Strides 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 Strides:

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 cirrhosis: 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)

- vomiting
- in patients with cirrhosis, exacerbation (increase in severity) of pruritus (itching) at the beginning of the treatment cannot be completely ruled out.
- in patients with stage IV primary biliary cirrhosis, 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ursodeoxycholic acid Strides

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 Strides 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 lauril sulphate (E487), maize starch, magnesium stearate (E572)
Capsule Shell: gelatin (E441), titanium dioxide (E 171)

What Ursodeoxycholic acid Strides looks like and contents of the pack

Ursodeoxycholic acid Strides 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 Strides 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 (Cyprus) Limited,
Themistokli Dervi 3,
JULIA house, 1st floor
1066 Nicosia,
Cyprus

Manufacturer

Fairmed Healthcare GmbH
Maria-Goeppert-Straße 3
23562 Lübeck
Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria:	Ursodeoxycholsäure Strides 250mg Hartkapseln
Belgium:	Ursodeoxycholzuur Strides 250mg harde capsules
Czech Republic:	Ursodeoxycholová kyselina Strides 250mg tvrdé tobolky
Germany:	Ursodeoxycholsäure Strides 250mg Hartkapseln
Greece:	Ursodeoxycholic acid Strides 250mg Hard Capsules
Hungary:	Ursodeoxikólsav Strides 250mg kemény kapszula
Ireland:	Ursodeoxycholic acid Strides 250mg Hard Capsules
Netherlands:	Ursodeoxycholzuur Strides 250mg harde capsules
Poland:	Ursodeoxycholic acid Strides
Romania:	Acid ursodeoxicolic Strides Arcolab International Ltd 250mg Capsule
Slovak Republic:	Ursodeoxycholová kyselina Strides 250mg tvrdé kapsuly
United Kingdom:	Ursodeoxycholic acid 250mg Hard Capsules

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