

## **Package leaflet: Information for the patient**

### **Ursodeoxycholic Acid 250 mg hard capsule**

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 use Ursodeoxycholic Acid
3. How to use 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 (UDCA), the active substance from Ursodeoxycholic Acid is a bile acid produced naturally, which is found in small amounts in human bile.

#### **Ursodeoxycholic Acid is used for:**

- 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
- 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 liver disease associated with a condition called cystic fibrosis in children 6 to 18 years.

#### **2. What you need to know before you use Ursodeoxycholic Acid**

##### **Do not use Ursodeoxycholic Acid:**

- If you are allergic to bile acids like UDCA or any of the other ingredients of this medicine (listed in section 6).
- If you have an acute inflammation of the gall bladder or biliary tract.
- If you have a blockage of the common bile duct or cystic duct (obstruction of the biliary tract).
- If you have frequent cramp-like upper abdomen pain (biliary colic).
- If your doctor has said you have calcified gallstones.
- If you have an insufficiency of the contractility of the gall bladder.
- If you are or have a child with biliary atresia or has 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.

## **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Ursodeoxycholic Acid. Ursodeoxycholic Acid should be administered 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.

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

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

If you suffer from primary biliary cirrhosis and your symptoms get worse at the beginning of the treatment a reduction in the dose may be required and gradually increased again as described in section 3 (How to take Ursodeoxycholic Acid).

If you are a woman of childbearing potential you must use contraception. Non-hormonal or oral contraceptives containing small amounts of estrogen are recommended. However, if you take Ursodeoxycholic Acid for dissolve gallstones, you should use non-hormonal contraception because hormonal contraceptives may increase gallstone risk.

## **Other medicines and Ursodeoxycholic Acid**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those without medical 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 (drugs that bind hydrochloric acid in the gastric juice) 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 Ursodeoxycholic Acid.
- rosuvastatin (used to lower blood lipids). It may be necessary for your doctor to alter the dose of these medicines.
- 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.

## **Ursodeoxycholic Acid may increase the effects of the following medicines:**

- 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.

If you are taking Ursodeoxycholic Acid 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 Ursodeoxycholic Acid.

## **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.

### *Pregnancy*

You should not take Ursodeoxycholic Acid during pregnancy unless your doctor thinks it is absolutely necessary. The use of Ursodeoxycholic Acid during the first 3 months of pregnancy may cause foetal harm.

Check that you are not pregnant before taking this medicine

### *Women of child-bearing potential*

Even if you are not pregnant you should talk to your doctor because women of childbearing potential must use contraception. Non-hormonal or oral contraceptives containing small amounts of estrogen are recommended. However, if you take Ursodeoxycholic Acid for dissolve gallstones, you should use non-hormonal contraception because hormonal contraceptives may increase gallstone risk.

Your doctor must exclude the possibility of a pregnancy before beginning of treatment.

### *Breastfeeding*

You should not take Ursodeoxycholic Acid during breast-feeding. It is not known whether Ursodeoxycholic Acid passes into breast milk. If treatment with Ursodeoxycholic Acid is absolutely necessary, you should stop breastfeeding.

### **Driving and using machines**

Ursodeoxycholic Acid has no or negligible influence on the ability to drive and use machines.

## **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.

The daily dose is determined by therapeutic indication.

### *For the treatment of the of primary biliary cirrhosis (PBC)*

The recommended daily dose will be determined by the doctor based on body weight and is between 3 to 7 hard capsules of Ursodeoxycholic Acid (12 – 16 mg of UDCA per kg of body weight per day).

During the first 3 months of treatment you should take Ursodeoxycholic Acid in the morning, to midday and evening.

The recommended treatment schedule is as follows:

<b>Body weight (kg)</b>	<b>Daily dose (mg/ kg of body weight)</b>			
		<b>Morning</b>	<b>Midday</b>	<b>Evening</b>
47 – 62 kg	12-16	1	1	1
63 – 78 kg	13-16	1	1	2
79 – 93 kg	13-16	1	2	2
94 – 109 kg	14-16	2	2	2
Over 110 kg	7 hard capsules	2	2	3

With improvement of the liver values your doctor will advise to take the daily dose once daily in the evening.

The use of Ursodeoxycholic Acid in primary biliary cirrhosis may be continued indefinitely.

### *For dissolution of cholesterol gallstones:*

Adults: The usual dose is 8–12 mg/ ursodeoxycholic acid (UDCA) per kg body weight per day, taken in the evening before bedtime according to:

- up to 60 kg: 2 capsules
- 61-80 kg: 3 capsules
- 81-100 kg: 4 capsules

- above 100 kg: 5 capsules

Care should be taken to ensure that they are taken regular.

In general, the time required for dissolution of gallstones is generally 6-24 months, depending on stone size and composition.

Every 6 months the doctor will check the effectiveness of treatment (reduction in size until such calculi) by radiographic examination (cholecystography) or ultrasound.

Your doctor may stop treatment unless noted a reduction in the size of gallstones after 2 cholecystography and/or successive ultrasound.

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

The recommended dose is 20mg per kg of body weight daily taken in 2 or 3 divided doses. It may be increased if necessary to 30mg per kg of body weight daily.

Body weight BW (kg)	Daily dose (mg/kg BW)	Ursodesoxycholic Acid 250mg 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

Take the capsules two to three times a day as advised for your doctor or pharmacist. Take the capsules regularly.

#### *How to use Ursodeoxycholic Acid*

Swallow the capsules whole with a glass of water.

#### **Elderly**

There is no evidence to suggest that any alteration in the adult dose is needed.

#### **Use in children and adolescents**

Cholesterol rich gallstones are very rare in children but when they occur, dosage should be related to bodyweight and medical conditions.

There is no age limit for ursodeoxycholic acid administration, the active ingredient of Ursodeoxycholic Acid. 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**

Diarrhoea may occur as a result of overdose. Please inform your doctor immediately if you have persistent diarrhoea. Make sure you drink enough liquids to replace your fluid and salt balance.

#### **If you forget to take Ursodeoxycholic Acid**

Do not take more doses the next time, but just continue the treatment with the prescribed dose. 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 decide to stop your treatment early.

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

#### **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.

**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 cirrhosis which partially eases after treatment is discontinued
- hardening of gallstones due to build-up of calcium
- 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 via Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://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 Ursodeoxycholic Acid**

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

The medicinal product does not require any special storage conditions.

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.

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.
- The other ingredients are: hard capsule contents: StarCap (maize starch, pregelatinized starch), crospovidone (E1202), sodium lauryl sulphate, silica colloidal anhydrous, magnesium stearate (E572), capsule: gelatine (E441), sunset yellow (E110), titanium dioxide (E171).

##### **What Ursodeoxycholic Acid looks like and contents of the pack**

Hard gelatin capsules, orange, containing white or almost white granules.

Box of 3 blisters packs PVC-PVDC/Aluminium, each containing 10 hard capsules.

Box of 5 blisters packs PVC-PVDC/Aluminium, each containing 10 hard capsules.  
Box of 3 blisters packs PVC-PVDC/Aluminium, each containing 20 hard capsules.  
Box of 5 blisters packs PVC-PVDC/Aluminium, each containing 20 hard capsules.  
Box of 10 blisters packs PVC-PVDC/Aluminium, each containing 20 hard capsules.

Not all pack sizes may be marketed.

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