

Package leaflet: Information for the user

Ursodeoxycholic Acid Capsules 250mg (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

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

Ursodeoxycholic Acid Capsules contain ursodeoxycholic acid (UDCA) as the active substance. UDCA is a bile acid normally only found in small amounts in human bile. Ursodeoxycholic Acid Capsules are used to dissolve gallstones that are rich in cholesterol. Ursodeoxycholic Acid Capsules are also used in the treatment of a condition called primary biliary cirrhosis and 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 Capsules

Do not take Ursodeoxycholic Acid Capsules

- if you have acute inflammation of the gall bladder or biliary tract
- if you have a blockage of the biliary tract
- if you have frequent episodes of biliary colic (recurrent pain in the upper abdomen)
- if your gall bladder does not work correctly
- if you have gallstones that are visible on an x-ray
- if you are pregnant or you think you might be pregnant
- if there is a chance you might become pregnant
- if you have a stomach or duodenal ulcer
- if you have a stoma because part of your bowel has been removed
- if you suffer from any liver problems (apart from primary biliary cirrhosis and liver problems associated with cystic fibrosis in children aged 6 years to less than 18 years)
- if you are allergic to ursodeoxycholic acid (UDCA) or any of the other ingredients of this medicine (listed in section 6).

Children with a condition where their 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 Capsules.

Talk to your doctor, pharmacist or nurse if any of the above apply to you.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Ursodeoxycholic Acid Capsules.

Ursodeoxycholic Acid Capsules must be used under medical supervision. Your doctor should test your liver function regularly every four weeks for the first three months of treatment. After this time, it should be monitored at three month intervals.

Please inform your doctor immediately if you have diarrhoea, as this might require a reduction in the dose or discontinuation of the treatment with Ursodeoxycholic Acid Capsules.

If you are being treated for gallstones, your doctor will monitor the progress of the dissolution of your gallstones.

If you are being treated for primary biliary cirrhosis, in rare cases your symptoms may worsen at the beginning of your treatment e.g. the itching may increase. If this happens please inform your doctor immediately, as you might require a reduction in your dose of Ursodeoxycholic Acid Capsules.

Excessive dietary intake of calories and cholesterol should be avoided while you are taking Ursodeoxycholic Acid Capsules.

Other medicines and Ursodeoxycholic Acid Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those listed below:

- Colestyramine, colestipol (medicines to lower your blood cholesterol level), charcoal or antacids containing aluminium (indigestion remedies). If you must take a medicine containing any of these ingredients, it should be taken at least two hours before or after Ursodeoxycholic Acid Capsules.
- ciclosporin (an immunosuppressant)
- ciprofloxacin or dapsone (antibiotics)
- rosuvastatin or clofibrate (used to lower cholesterol)
- oral contraceptives or any other female hormones, such as estrogenic hormones or hormone replacement therapy (HRT). Female patients taking Ursodeoxycholic Acid Capsules for the dissolution of gallstones should only use non-hormonal contraceptive methods e.g. barrier methods, because hormonal contraceptives may stimulate the formation of gallstones.

It may still be safe for you to take Ursodeoxycholic Acid Capsules, your doctor or pharmacist will be able to advise you.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy, breast-feeding and fertility

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy or while breast-feeding.

In the absence of adequate evidence of safety in pregnancy, Ursodeoxycholic Acid Capsules should not be taken if you are pregnant, think you might be pregnant or are trying to become pregnant.

Use a reliable method of contraception during treatment with Ursodeoxycholic Acid Capsules. Female patients taking Ursodeoxycholic Acid Capsules for the dissolution of gallstones should only use non-hormonal contraceptive methods e.g. barrier methods, because hormonal contraceptives may stimulate the formation of gallstones.

The levels of the active ingredient of this medicine in breast milk are low and are not expected to cause your baby any problems.

Driving and using machines

Ursodeoxycholic Acid Capsules will have little or no influence on your ability to drive or use machines.

3. How to take Ursodeoxycholic Acid Capsules

Always take Ursodeoxycholic Acid Capsules exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure. Your doctor will advise you of the dose you should take.

Ursodeoxycholic Acid Capsules should be taken orally (by mouth). The recommended dose which is used to dissolve cholesterol-rich gallstones in adults is two or three capsules daily, taken in two divided doses after meals. The recommended adult dose for the treatment of primary biliary cirrhosis is two to five capsules daily, taken in two to four divided doses. However, these doses may vary depending on your body weight.

Elderly patients will be prescribed a dose depending on their body weight.

Use in children and adolescents

The dose for the dissolution of cholesterol-rich gallstones in children is calculated using their body weight and is 8-10mg per kg of body weight per day, taken in two divided doses after meals.

The dose for children with cystic fibrosis, aged 6 years to less than 18 years, is calculated using their body weight. The usual daily starting dose is 20mg per kg of body weight in two to three divided doses, with a further increase to 30mg per kg of body weight per day if necessary.

The label on the container will tell you exactly how many capsules to take and how often. You should check with your doctor or pharmacist if you are not sure.

In patients with primary biliary cirrhosis, the symptoms may worsen at the start of treatment, e.g. 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 Capsules. Each week, your doctor will then gradually increase the daily dose, until you reach the required dose.

If you have any questions about the dose you have been prescribed please ask your doctor or pharmacist.

You may need to take Ursodeoxycholic Acid Capsules for many months for them to work. During this time your doctor will monitor your condition.

If you take more Ursodeoxycholic Acid Capsules than you should

This may cause diarrhoea. If you take too many capsules, contact your nearest hospital casualty department or doctor immediately. Take this leaflet and any remaining capsules with you to show the doctor.

If you forget to take Ursodeoxycholic Acid Capsules

If you miss a dose, take it as soon as you remember and then continue as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Ursodeoxycholic Acid Capsules

Do not stop taking Ursodeoxycholic Acid Capsules without first checking with your doctor.

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, Ursodeoxycholic Acid Capsules can cause side effects, although not everybody gets them.

Diarrhoea is a side effect that has been reported commonly (may affect up to 1 in 10 people). Please inform your doctor immediately if you have diarrhoea, as this might require a reduction in the dose or discontinuation of the treatment with Ursodeoxycholic Acid Capsules.

If you are being treated for primary biliary cirrhosis, in rare cases your symptoms may worsen at the beginning of your treatment e.g. the itching may increase. If this happens please inform your doctor immediately, as you might require a reduction in your dose of Ursodeoxycholic Acid Capsules.

Other side effects

The following side effect is common (may affect up to 1 in 10 people):

- pasty stools.

The following side effects are very rare (may affect up to 1 in 10,000 people):

- during the treatment of primary biliary cirrhosis: severe right upper abdominal pain, worsening of liver disease – this partially improves after treatment is stopped
- hardening of gallstones due to build up of calcium
- a red itchy rash.

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 the Yellow Card Scheme website: 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 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 container. The expiry date refers to the last day of that month.

This medicine should be stored at normal room temperature (below 25°C).

Do not use this medicine if you notice that the container or any of the capsules are damaged.

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 Capsules contain

The active substance is ursodeoxycholic acid (UDCA). Each Ursodeoxycholic Acid Capsule contains 250mg of ursodeoxycholic acid.

The powder in the capsule shells also contains other ingredients: microcrystalline cellulose and magnesium stearate. The capsule shells are made of gelatin and contain titanium dioxide (E171), erythrosine (E127) and quinoline yellow (E104) as colouring agents. The ink on the capsule shells contains shellac, black iron oxide (E172) and propylene glycol.

What Ursodeoxycholic Acid Capsules look like and the contents of the pack

Ursodeoxycholic Acid Capsules are ivory coloured gelatin capsules marked 'UDCA 250mg' in black ink.

Ursodeoxycholic Acid Capsules are available in packs of 2, 3, 4, 6, 9, 12, 14, 21, 28, 30, 56, 60, 84, 90, 100, 112, 120, 250 and 500 capsules. Not all pack sizes may be marketed. (Delete as appropriate)

Marketing Authorisation Holder

Galen Limited
Seagoe Industrial Estate
Craigavon
BT63 5UA
UK

Manufacturer

Almac Pharma Services Limited

Almac House

20 Seagoe Industrial Estate

Craigavon

BT63 5QD

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