

PX720/1 **PACKAGE LEAFLET:  
INFORMATION FOR THE USER**

# **Ursogal<sup>®</sup>** **Capsules 250mg** (Ursodeoxycholic acid)

**Read all of this leaflet carefully before you start taking this medicine.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Ursogal is and what it is used for
2. Before you take Ursogal Capsules
3. How to take Ursogal Capsules
4. Possible side effects
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6. Further information

#### **1. WHAT URSOGAL IS AND WHAT IT IS USED FOR**

Ursogal Capsules contain ursodeoxycholic acid (UDCA) as the active substance. Ursogal Capsules are used to dissolve gallstones that are rich in cholesterol. Ursogal Capsules are also used in the treatment of a condition called primary biliary cirrhosis.

#### **2. BEFORE YOU TAKE URSOGAL CAPSULES**

##### **Do not take Ursogal Capsules**

- if you are allergic (hypersensitive) to ursodeoxycholic acid (UDCA) or any of the other ingredients of Ursogal Capsules
- if you have any other types of gallstones known as radio-opaque or non-cholesterol gallstones
- if you have a gallbladder that no longer works
- if you are pregnant or you think you might be pregnant
- if there is a chance you might become pregnant
- if you suffer from any gastrointestinal problems such as gastric or duodenal ulcers
- if you have a stoma
- if you suffer from any liver problems (apart from primary biliary cirrhosis)

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

##### **Take special care with Ursogal Capsules**

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

##### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines, including those medicines obtained without a prescription:

- oral contraceptives or any other female hormones, such as oestrogenic hormones or hormone replacement therapy (HRT)
  - medicines to lower your blood cholesterol level, such as clofibrate, cholestyramine or colestipol
  - indigestion remedies
  - ciclosporin (an immunosuppressant)
- It may still be safe for you to take Ursogal 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.

##### **Taking Ursogal Capsules with food and drink**

Excessive dietary intake of calories and cholesterol should be avoided.

##### **Pregnancy and breast-feeding**

In the absence of adequate evidence of safety in pregnancy, Ursogal Capsules should not be taken if you are pregnant, think you might be pregnant or are trying to become pregnant. Ask your doctor or pharmacist for advice before taking any medicine during pregnancy or while breast-feeding.

##### **Driving and using machines**

Ursogal Capsules will have no influence on your ability to drive or use machines.

#### **3. HOW TO TAKE URSOGAL CAPSULES**

Always take Ursogal Capsules exactly as your doctor 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.

Ursogal Capsules should be taken orally (by mouth). The usual adult dose, which is used to dissolve cholesterol-rich gallstones, is two or three capsules daily, taken in two divided doses after meals. The usual 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. 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.

Elderly patients and children will be prescribed a dose depending on their body weight. If you have any questions about the dose you have been prescribed please ask your doctor or pharmacist.

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

#### **If you take more Ursogal Capsules than you should**

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 Ursogal 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 have any further questions on the use of this product, ask your doctor or pharmacist.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Ursogal Capsules can cause side effects, although not everybody gets them.

Diarrhoea is a side effect that has been reported. If you consider that this side effect is getting serious or if you notice any other side effects, please tell your doctor or pharmacist.

#### **5. HOW TO STORE URSOGAL CAPSULES**

Keep out of the reach and sight of children.

Do not use Ursogal Capsules after the expiry date, which is stated on the container. The expiry date refers to the last day of that month.

This product should be stored at normal room temperature (below 25°C). Do not use Ursogal Capsules if you notice that the container or any of the capsules are damaged.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist to dispose of medicines no longer required. These measures will help to protect the environment.

#### **6. FURTHER INFORMATION**

##### **What Ursogal Capsules contain**

The active substance is ursodeoxycholic acid (UDCA). Each Ursogal 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 Ursogal Capsules look like and the contents of the pack**

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

Ursogal Capsules are available in packs of 60 capsules.

##### **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  
UK

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**Ursogal is a trademark.**



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