

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

**Ursogal®
Tablets 150mg**

(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 Tablets
3. How to take Ursogal Tablets
4. Possible side effects
5. How to store Ursogal Tablets
6. Further information

1. WHAT URSOGAL IS AND WHAT IT IS USED FOR

Ursogal Tablets contain ursodeoxycholic acid (UDCA) as the active substance. Ursogal Tablets are used to dissolve gallstones that are rich in cholesterol.

2. BEFORE YOU TAKE URSOGAL TABLETS

Do not take Ursogal Tablets

- if you are allergic (hypersensitive) to ursodeoxycholic acid (UDCA) or any of the other ingredients of Ursogal Tablets
 - 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
- Talk to your doctor or pharmacist if any of the above apply to you.

Take special care with Ursogal Tablets

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

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 Tablets, 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 Tablets 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 Tablets 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 Tablets will have no influence on your ability to drive or use machines.

Ursogal Tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE URSOGAL TABLETS

Always take Ursogal Tablets 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 Tablets should be taken orally (by mouth). The usual adult dose is three or four tablets daily, taken in two divided doses after meals. However, this dose may vary depending on your body weight.

The label on the container will tell you exactly how many tablets 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 Tablets for many months for them to work. During this time your doctor will monitor your condition.

If you take more Ursogal Tablets than you should

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

If you forget to take Ursogal Tablets

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 Tablets 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 TABLETS

Keep out of the reach and sight of children.

Do not use Ursogal Tablets 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 Tablets if you notice that the container or any of the tablets 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 Tablets contain

The active substance is ursodeoxycholic acid (UDCA). Each Ursogal Tablet contains 150mg of ursodeoxycholic acid.

Ursogal Tablets also contain other ingredients; they are lactose, microcrystalline cellulose and magnesium stearate.

What Ursogal Tablets look like and the contents of the pack

Ursogal Tablets are round, white, uncoated, scored tablets marked 'UDCA 150mg'.

Ursogal Tablets are available in packs of 60 tablets.

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

This leaflet was last revised in 12/2011

Ursogal is a trademark.



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