

**PACKAGE LEAFLET : INFORMATION FOR THE USER**  
**Ursodeoxycholic Acid 300mg Film-Coated Tablets**  
**Ursodeoxycholic Acid**



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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

The name of your medicine is Ursodeoxycholic Acid 300mg Film-Coated Tablets. In the rest of this leaflet it is called Ursodeoxycholic Acid Tablets.

**In this leaflet:**

1. What Ursodeoxycholic Acid Tablets are and what they are used for
2. Before you take Ursodeoxycholic Acid Tablets
3. How to take Ursodeoxycholic Acid Tablets
4. Possible side effects
5. How to store Ursodeoxycholic Acid Tablets
6. Further information

## 1. WHAT URSODEOXYCHOLIC ACID TABLETS ARE AND WHAT THEY ARE USED FOR

The active ingredient in Ursodeoxycholic Acid Tablets is ursodeoxycholic acid, which is a naturally occurring substance (bile acid) normally present in the bile.

Ursodeoxycholic Acid Tablets may be used for the following:

- To dissolve certain types of gall stones (stones in the gall bladder), which contain cholesterol. Ursodeoxycholic Acid Tablets may be suitable for patients who are unable to have surgery or do not wish to have surgery.
- To treat a type of liver disease known as primary biliary cirrhosis (PBC).
- To treat liver disease associated with cystic fibrosis in children aged 6 years to less than 18 years.

## 2. BEFORE YOU TAKE URSODEOXYCHOLIC ACID TABLETS

**Do not take Ursodeoxycholic Acid Tablets if you:**

- are pregnant, planning to become pregnant or are breastfeeding

**or if you have:**

- ever had an allergic reaction to bile acids or to any of the other ingredients in Ursodeoxycholic Acid Tablets (see 'What Ursodeoxycholic Acid Tablets Contain' in section 6 'Further Information')
- a gall bladder which is not working properly or you have gall-stones that contain calcium
- severe liver disease other than primary biliary cirrhosis
- peptic ulcers
- inflammation of the bowel
- inflammation of the gall bladder or biliary tract (the ducts that transport bile from the liver to the small intestine)
- blockage of the biliary tract
- frequent episodes of biliary colic (often characterised by upper right stomach pain).

If any of the above statements apply to you, do not take Ursodeoxycholic Acid Tablets.

**Children aged 6 years to less than 18 years with cystic fibrosis**

Not to be taken if the child has had unsuccessful surgery to restore the flow of bile to the small intestine.

**Taking other medicines**

Taking another medicine while you are taking Ursodeoxycholic Acid Tablets can affect how it or the other medicine works. Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including those you may have bought yourself without a prescription.

Please check with your doctor if you are taking any of the following (or any other medication):

- oral contraceptives (the pill) or oestrogen (a female sex hormone)
- medicines used to lower blood cholesterol (clofibrate, colestipol and colestyramine). If it is necessary to take a medicine containing colestipol or colestyramine, you must take it at least 2 hours before or after Ursodeoxycholic Acid Tablets
- medicines used to treat stomach problems (charcoal and antacids containing aluminium). If it is necessary to take one of these medicines, you must take it at least 2 hours before or after Ursodeoxycholic Acid Tablets
- ciclosporin (used after transplants)
- ciprofloxacin (used to treat infections)
- nitrendipine (used to treat high blood pressure)
- dapsone (used to treat leprosy and other skin conditions).

If you have any doubts about whether you should take this medicine then discuss matters with your doctor before taking it.

**Pregnancy and breast-feeding**

You should **not** take Ursodeoxycholic Acid Tablets if you are pregnant or trying to become pregnant.

You should use extra contraceptive precautions that do not contain hormones (e.g. condoms, caps or certain coils) whilst taking Ursodeoxycholic Acid Tablets (but see precautions above in "Taking other medicines" section).

If at any point during treatment with Ursodeoxycholic Acid Tablets you think you might have become pregnant, contact your doctor **immediately**.

You should not breast-feed whilst taking Ursodeoxycholic Acid Tablets.

**Driving and operating machines**

Ursodeoxycholic Acid Tablets do not affect the ability to drive or operate machinery.

**Important information for patients who have an intolerance to some sugars**

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

## 3. HOW TO TAKE URSODEOXYCHOLIC ACID TABLETS

Your doctor will decide the dose which is best for you. Always follow your doctor's instructions completely and also follow any special instructions or warnings which appear on the label which the pharmacist has put on the package. If you do not understand, or are in any doubt, ask your doctor or pharmacist.

Unless instructed differently, take your tablets with a drink of water.

During treatment you should have regular blood tests to check your liver function.





### Adults and Elderly

#### To dissolve gall stones that contain cholesterol

The usual daily dose is one to three tablets depending on your weight, either in divided doses or as a single night time dose.

Your doctor may tell you to take Ursodeoxycholic Acid Tablets for up to two years depending on the size of your gall-stone. You should continue your treatment for three months after your stone appears to have gone.

#### To treat primary biliary cirrhosis

The usual daily dose is two to four tablets, depending on your weight, to be taken in two to four divided doses.

### Children

The dose for a child may be less than the usual adult dose. The doctor will calculate the dose depending on the child's weight.

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

The dose will be calculated by the doctor depending on the child's weight.

#### If you take more Ursodeoxycholic Acid Tablets than you should

Too many Ursodeoxycholic Acid Tablets may cause diarrhoea. If you accidentally take too many tablets contact your doctor, pharmacist or nearest hospital casualty department. Take this leaflet and any remaining tablets with you to show the doctor or pharmacist.

#### If you miss a dose of Ursodeoxycholic Acid Tablets

If you forget to take a dose, take another as soon as you remember. If it is almost time for your next dose, then do not take the missed dose at all. Do not take a double dose to make up for a forgotten tablet.

#### Stopping Ursodeoxycholic Acid Tablets

You should continue to take Ursodeoxycholic Acid Tablets for as long as your doctor tells you to. Do not stop taking the medicine without talking to your doctor first.

## 4. POSSIBLE SIDE EFFECTS

Like many medicines Ursodeoxycholic Acid Tablets may cause side effects in some patients, although not everybody gets them.

The following side effects are common (affect less than 1 out of 10 people):

- pasty stools
- diarrhoea.

The following side effects are very rare (affect less than 1 out of 10,000 people):

- severe right upper stomach pain
- worsening of liver disease
- a red, itchy rash ('hives').



The following side effects may also occur (how often these side effects occur is not known):

- feeling sick
- being sick
- itching.

Very rarely gall-stones get a layer of calcium on them, which may mean you will need an operation to remove them.

#### 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 at: [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 TABLETS

#### Keep out of the reach and sight of children.

Do not take this medicine if the expiry date on the label has passed. The expiry date refers to the last day of that month.

Ursodeoxycholic Acid Tablets should not be taken if they show signs of deterioration. Do not store above 25°C.

Store in the original container or package in order to protect from light and moisture. Do not transfer the tablets to another container.

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

## 6. FURTHER INFORMATION

#### What Ursodeoxycholic Acid Tablets contain

The active ingredient in Ursodeoxycholic Acid Tablets is ursodeoxycholic acid. Each tablet contains 300mg.

The other ingredients are lactose, maize starch, povidone, sodium starch glycollate, magnesium stearate, hydroxypropylmethylcellulose (E464), titanium dioxide (E171), polyethylene glycol and purified water.

#### What Ursodeoxycholic Acid Tablets look like and contents of the pack

The tablets are white, film-coated, have a curved shape and are marked "Urdox" on one side.

Ursodeoxycholic Acid Tablets are available in polyethylene/polypropylene (plastic) containers containing 60, 100 or 500 tablets and in blister strips of 60 tablets in cartons.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder:** Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

**Manufacturer:** CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

#### Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

**0800 198 5000 (UK Only)**

Please be ready to give the following information:

Product name	Reference number
Ursodeoxycholic Acid 300mg Film-Coated Tablets	29831/0198

This is a service provided by the Royal National Institute of Blind People.

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