

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

### **Ursodeoxycholic acid 250 mg capsules, hard** 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**

1. What Ursodeoxycholic acid capsules are and what they are used for
2. What you need to know before you take Ursodeoxycholic acid capsules
3. How to take Ursodeoxycholic acid capsules
4. Possible side effects
5. How to store Ursodeoxycholic acid capsules
6. Contents of the pack and other information

#### **1. What Ursodeoxycholic acid capsules are and what they are used for**

Ursodeoxycholic acid capsules contains the active substance ursodeoxycholic acid which is a naturally occurring bile acid which is found in small amounts in human bile.

Ursodeoxycholic acid capsules are used:

- 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 (PBC).
- to dissolve gallstones caused by excess cholesterol in the gall bladder 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 aged 6 to 18 years.

#### **2. What you need to know before you take Ursodeoxycholic acid capsules**

##### **Do not take Ursodeoxycholic acid capsules:**

- if you are allergic to ursodeoxycholic acid or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to bile acids
- if your gall bladder does not work properly
- if your doctor have told you that you have calcified gallstones (visible on an x-ray)
- 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 pains in the upper abdomen (biliary colic)
- if you are a child with biliary atresia and have 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 or if you are unsure whether you have any of them.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Ursodeoxycholic acid capsules.

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 in the treatment of PBC, in rare cases the symptoms may worsen at the beginning of treatment. If this happens, please speak to your doctor about reducing your initial dose.

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

Please inform your doctor immediately if you have diarrhoea as this may require a reduction in the dose or discontinuation of treatment.

### **Other medicines and Ursodeoxycholic acid capsules**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

A reduction in the effects of the following medicines is possible when taking Ursodeoxycholic acid capsules:

- colestyramine, colestipol (to lower blood lipids) or antacids 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 capsules.
- ciprofloxacin and dapson (antibiotics), nitrendipine (used to treat high blood pressure). It may be necessary for your doctor to alter the dose of these medicines.

A change in the effects of the following medicines is possible when taking Ursodeoxycholic acid capsules:

- 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.
- rosuvastatin (for high cholesterol and related conditions).

Please inform your doctor if you are taking any blood cholesterol lowering agents such as clofibrate or medicines that contain oestrogen (estrogen) especially if you are taking Ursodeoxycholic acid capsules for the dissolution of gallstones, as they may stimulate the formation of gallstones.

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

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 capsules during pregnancy unless your doctor thinks it is absolutely necessary.

### Women of child-bearing potential

Even if you are not pregnant, you should still discuss this possibility with your doctor. Before starting treatment with Ursodeoxycholic acid capsules, your doctor will check that you are not pregnant and review your contraceptive method to make sure it is appropriate.

### Breast-feeding

It is not known if Ursodeoxycholic acid passes into breast milk. Therefore consult your doctor before use if you are breast-feeding or about to start breast-feeding.

### **Driving and using machines**

There are no known effects on the ability to drive or use machines.

## **3. How to take Ursodeoxycholic acid capsules**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### **For Primary biliary cirrhosis (chronic inflammation of the bile ducts):**

#### *Dosage*

During the first 3 months of treatment, you should take Ursodeoxycholic acid capsules in the morning, at midday and in the evening. As liver function values improve, the total daily dose may be taken once a day in the evening.

Body weight BW (kg)	Daily dose (mg/kg BW)	Ursodeoxycholic Acid 250 mg capsules			
		First 3 months			Subsequently
		Morning	Midday	Evening	Evening (once daily)
47 - 62	12 – 16	1	1	1	3
63 – 78	13 - 16	1	1	2	4
79 – 93	13 - 16	1	2	2	5
94 - 109	14 - 16	2	2	2	6
Over 110		2	2	3	7

#### *How to take Ursodeoxycholic acid capsules*

Swallow the capsules whole with a drink of water or other liquid. Take your medicine regularly.

#### *Duration of treatment*

Ursodeoxycholic acid capsules may be continued indefinitely in cases of PBC.

### **Dissolution of cholesterol gallstones:**

#### *Dosage*

The recommended dose in adults is: 10 mg/kg body weight daily, as follows:  
50-62 kg: 2 capsules daily

63-85 kg 3 capsules daily  
86-120 kg 4 capsules daily

*How to take Ursodeoxycholic acid capsules*

Swallow the capsules whole with a drink of water or other liquid. Take the capsules in the evening at bedtime. Take your medicine regularly.

*Duration of treatment*

It generally takes 6-24 months to dissolve gallstones. If there are no reduction in the size of the gallstones after 12 months, treatment should be stopped.

Every 6 months, your doctor should check whether the treatment is working. At each of these follow-up examinations, it should be checked whether a build-up of calcium causing hardening of the stones has occurred since the last time. If this happens, your doctor will stop the treatment.

**Both Indications:**

**Use in elderly:**

There is no evidence to suggest that any alteration in the adult dose is needed but your doctor will take your age and health into consideration.

**Use in children and adolescents**

The administration of Ursodeoxycholic acid capsules is based on body weight and the condition being treated.

**Use in children (6 to 18 years) for treatment of liver disease associated with cystic fibrosis:**

*Dosage*

The recommended daily dose is 20mg per kg body weight, divided in 2-3 doses. Your doctor may want to increase the dose further to 30mg per kg body weight daily if necessary.

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

*How to take Ursodeoxycholic acid capsules*

Take the capsules two to three times per day, as advised. Take the capsules regularly.

### *Duration of treatment*

Treatment can be continued long term (up to 12 years) in children with cystic fibrosis associated hepatobiliary disorders.

If you feel that the effect of Ursodeoxycholic acid capsules is too strong or too weak, please talk to your doctor or pharmacist.

### **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. If you do suffer from diarrhoea, make sure you drink enough liquids to replace your fluid and electrolyte balance.

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

Do not take a double dose to make up for a forgotten capsule, but just continue the treatment with the prescribed dose.

### **If you stop taking Ursodeoxycholic acid**

Always talk to your doctor before you decide to interrupt treatment with Ursodeoxycholic acid capsules or decide to stop your treatment early.

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, this medicine can cause side effects, although not everybody gets them.

*Common: may affect up to 1 in 10 people*

- Soft, loose stools or diarrhoea.

*Very rare: may affect up to 1 in 10,000 people*

- during the treatment of PBC: severe right-sided upper abdominal pain, severe worsening of liver scarring - this partially eases after treatment is stopped
- hardening of gallstones due to build up of calcium. There are no additional symptoms of this but it will show up in tests
- nettle rash (urticaria).

### **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:

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

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 carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 contains:**

- The active substance is ursodeoxycholic acid. Each capsules contain 250 mg ursodeoxycholic acid
- The other ingredients are magnesium stearate, maize starch, Silica colloidal anhydrous, titanium dioxide (E171) and gelatin.

### **What Ursodeoxycholic acid capsules looks like and contents of the pack**

Hard gelatin capsules with white body and cap filled with powder. The length of the capsules is  $21.7 \pm 0.3$  mm.

Blister (PVC/Alu): 25, 50, 60, 75, 100 capsules

Not all pack sizes may be marketed.

### **Manufacturer**

ABC Farmaceutici S.p.A.

Via Canton Moretti, 29 (Loc. Localita San Bernardo)

10015- Ivrea (TO)

### **Marketing Authorisation Holder**

Amdipharm Limited

Temple Chambers,

3 Burlington Road,

Dublin 4,

Ireland

### **This medicinal product is authorised in the Member States of the EEA under the following names:**

Belgium: Ursodeoxycholic acid amdipharm 250 mg gélules

Ireland: Ursodeoxycholic acid 250 mg capsules, hard

Luxembourg: Ursodeoxycholic acid 250 mg gélules

United Kingdom: Ursodeoxycholic acid 250 mg capsules, hard

**This leaflet was last revised in July 2021.**