

Product Name	UDCA 250g/5ml Oral Suspension
MA Number	PL 60170/0003
Component	Package Leaflet
Artwork Number	PL-URSO-C5-250-Rev 02-BN (ECL0)

Package leaflet: Information for the user

DEOXXA® 250 mg / 5 ml Oral Suspension 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The full name of your medicine is DEOXXA 250 mg / 5 ml Oral Suspension but it will be referred to as DEOXXA throughout this leaflet.

What is in this leaflet

1. What DEOXXA is and what it is used for
2. What you need to know before you take DEOXXA
3. How to take DEOXXA
4. Possible side effects
5. How to store DEOXXA
6. Contents of the pack and other information

1. What DEOXXA is and what it is used for

Ursodeoxycholic acid, the active substance in DEOXXA, is a naturally occurring bile acid. Small amounts of ursodeoxycholic acid are found in human bile.

DEOXXA is used:

- for the treatment of primary biliary cholangitis (PBC), 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
- 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 gallstones)
- for liver disease associated with a condition called cystic fibrosis in children aged 1 month to 18 years.

2. What you need to know before you take DEOXXA

Do not take DEOXXA if:

- you are allergic to ursodeoxycholic acid, to other bile acids or any of the other ingredients of this medicine (listed in section 6)
- your gall bladder does not work properly
- you have gallstones that are visible on an X-ray (calcified)
- you have acute inflammation of the gall bladder or biliary tract
- you have a blockage of the common bile duct or cystic duct (obstruction of the biliary tract)
- you have frequent cramp-like upper abdominal pain (biliary colic)
- you are a child with biliary atresia and have poor bile flow, even after surgery.

Please ask your doctor about any of 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 DEOXXA.

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 to dissolve gallstones, your doctor should arrange for a scan of your gallbladder after the first 6 – 10 months of treatment.

When used in the treatment of PBC, in rare cases the symptoms may worsen when you start treatment. Talk to your doctor if this happens as the dose may need to be reduced.

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 DEOXXA

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. The effects of these medicines may be altered:

- A **reduction in the effects** of the following medicines is possible when taking ursodeoxycholic acid:
- 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 this medicine
 - Ciprofloxacin and dapsone (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:
- 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 this medicine for the dissolution of gallstones as they may stimulate the formation of gallstones.

Pregnancy, breast-feeding and fertility

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 this medicine 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 this medicine, your doctor will check that you are not pregnant and review your contraceptive method to make sure it is appropriate.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding.

Driving and using machines

No particular precautions are necessary.

DEOXXA contains benzoic acid, propylene glycol, xylitol, ethanol and sodium

This medicine contains 7.5 mg benzoic acid in each 5 ml of suspension. Benzoic acid may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

This medicine contains 51.75 mg propylene glycol in each 5 ml of suspension. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

This medicine contains 1600 mg xylitol in each 5 ml of suspension. May have a laxative effect. The calorific value of xylitol is 2.4 kcal/g.

This medicine contains 1.5 mg alcohol (ethanol) in each 5 ml of suspension which is equivalent to 0.03% w/v. The amount in each 5 ml dose of this medicine is equivalent to less than 1 ml of beer or wine. The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains 11.07 mg sodium (main component of cooking / table salt) in each 5 ml of suspension. This is equivalent to 0.6 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take DEOXXA

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 treatment of primary biliary cholangitis (chronic inflammation of the bile ducts)

During the first 3 months of treatment, this medicine should be taken 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. The recommended dose is as follows:

Body Weight (BW) (kg)	Daily Dose (mg/kg BW)	Amount of Suspension (ml)			
		First 3 months			Subsequently
		Morning	Midday	Evening	Evening (1 x daily)
8 – 11	12 – 16	-	1.25 ml	1.25 ml	2.5 ml
12 – 15	12 – 16	1.25 ml	1.25 ml	1.25 ml	3.75 ml
16 – 19	13 – 16	2.5 ml	-	2.5 ml	5 ml
20 – 23	13 – 15	1.25 ml	2.5 ml	2.5 ml	6.25 ml
24 – 27	13 – 16	2.5 ml	2.5 ml	2.5 ml	7.5 ml
28 – 31	14 – 16	1.25 ml	2.5 ml	5 ml	8.75 ml
32 – 39	12 – 16	2.5 ml	2.5 ml	5 ml	10 ml
40 – 47	13 – 16	2.5 ml	5 ml	5 ml	12.5 ml
48 – 62	12 – 16	5 ml	5 ml	5 ml	15 ml
63 – 80	12 – 16	5 ml	5 ml	10 ml	20 ml
81 – 95	13 – 16	5 ml	10 ml	10 ml	25 ml
96 – 115	13 – 16	10 ml	10 ml	10 ml	30 ml
Over 115	-	10 ml	10 ml	15 ml	35 ml

Duration of treatment

Take this medicine regularly. Ursodeoxycholic acid may be continued indefinitely in cases of primary biliary cholangitis.

To dissolve cholesterol gallstones

The recommended dose is approximately 10 mg per kg body weight daily as follows:

Body Weight (kg)	Amount of Suspension (ml)
5 – 7	1.25 ml
8 – 12	2.50 ml
13 – 18	3.75 ml
19 – 25	5 ml
26 – 35	7.5 ml
36 – 50	10 ml
51 – 65	12.5 ml
66 – 80	15 ml
81 – 100	20 ml
Over 100	25 ml

How to take DEOXXA

Take the suspension in the evening at bedtime. Take the suspension regularly.

Duration of treatment

It generally takes 6-24 months to dissolve gallstones. If there is no reduction in the size of the gallstones after 12 months, therapy 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 children and adolescents:

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

Use in children (1 month to 18 years) for treatment of liver disease associated with cystic fibrosis

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

Single doses for children with a body weight up to 10 kg should be given with an oral syringe as the spoon provided does not cover volumes below 1.25 ml. Use a 2 ml oral syringe with a graduation of 0.1 ml.

Please note: Oral syringes are not included in the pack but may be purchased from your pharmacist.

To administer the required dose by syringe:

1. Shake the bottle well before opening
2. Pour a small amount of suspension into a glass
3. Draw the appropriate volume into the syringe
4. Tap against the barrel of the syringe to remove any large air bubbles
5. Check the appropriate volume of suspension is in the syringe, adjust if necessary
6. Carefully dispense the syringe contents directly into the child's mouth
7. Wash the syringe with water after each use and allow it to dry completely before you next use it.

Do **NOT** put the syringe into the bottle. Do **NOT** put unused suspension from the syringe or the glass back into the bottle.

Up to 10 kg body weight: Dosing 20 mg ursodeoxycholic acid/kg/day

Measuring device: 2 ml graduated oral syringe (not provided).

Body Weight (kg)	Amount of Suspension (ml)	
	Morning	Evening
4	0.8	0.8
4.5	0.9	0.9
5	1.0	1.0
5.5	1.1	1.1
6	1.2	1.2
6.5	1.3	1.3
7	1.4	1.4
7.5	1.5	1.5
8	1.6	1.6
8.5	1.7	1.7
9	1.8	1.8
9.5	1.9	1.9
10	2.0	2.0

The spoon provided can be used for children over 10 kg body weight.

More than 10 kg body weight: Dosing 20-25 mg ursodeoxycholic acid/kg/day

Measuring device: Spoon

Body Weight (kg)	Daily Dose UDCA (mg/kg BW)	Amount of Suspension	
		Morning	Evening
11 – 12	21 – 23	2.5 ml	2.5 ml
13 – 15	21 – 24	2.5 ml	3.75 ml
16 – 18	21 – 23	3.75 ml	3.75 ml
19 – 21	21 – 23	3.75 ml	5 ml
22 – 23	22 – 23	5 ml	5 ml
24 – 26	22 – 23	5 ml	6.25 ml
27 – 29	22 – 23	6.25 ml	6.25 ml
30 – 32	21 – 23	6.25 ml	7.5 ml
33 – 35	21 – 23	7.5 ml	7.5 ml
36 – 38	21 – 23	7.5 ml	8.75 ml
39 – 41	21 – 22	8.75 ml	8.75 ml
42 – 47	20 – 22	8.75 ml	10 ml
48 – 56	20 – 23	11.25 ml	11.25 ml
57 – 68	20 – 24	13.75 ml	13.75 ml
69 – 81	20 – 24	16.25 ml	16.25 ml
82 – 100	20 – 24	20 ml	20 ml
>100	-	22.5 ml	22.5 ml

Conversion table:

Amount of Suspension	Ursodeoxycholic Acid
5 ml	250 mg
3.75 ml	187.5 mg
2.5 ml	125 mg
1.25 ml	62.5 mg

How to take DEOXXA

Take your medicine two to three times per day, as advised. Take this medicine regularly.

Duration of treatment

Treatment can be continued long term (up to 18 years) in children with cystic fibrosis associated hepatobiliary disorders.

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

Method of administration

For oral administration.

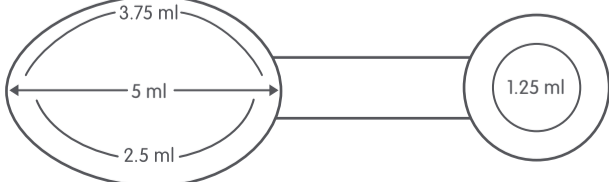
Always shake the closed bottle well before use.

A 5ml measuring spoon with graduations of 1.25 ml, 2.5 ml, 3.75 ml and 5 ml is provided and can be used to deliver the majority of doses e.g. 6.25 ml is given as 1 x 5 ml and 1 x 1.25 ml and 8.75 ml is given as 1 x 5 ml and 1 x 3.75 ml. Pour the suspension into the spoon to the required dose – see diagram below – and then swallow the medicine. Repeat as required for further doses. Ensure you rinse the spoon with water after each use and allow to dry. A measuring cup or oral syringe (not supplied) can also be used if available.

Doses under 2 ml for children with cystic fibrosis weighing under 10 kg should be administered with a 2 ml oral syringe (not supplied).

This medicine can be administered via a gastric, duodenal or nasal feeding tube if required. Larger tubes should be rinsed twice with at least 10 ml of water following administration while smaller tubes should be rinsed at least once with a minimum of 3 ml of water.

Measuring spoon:



If you take more DEOXXA than you should, you are likely to suffer from diarrhoea. If you or anyone else take more of this medicine than you should, contact your doctor or nearest hospital casualty department as soon as possible. Take the bottle and this leaflet with you so the medical staff will know what you have taken.

If you forget to take DEOXXA

Take the next dose at the correct time and then go on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking DEOXXA

Always speak to your doctor before you decide to interrupt treatment with ursodeoxycholic acid or to stop your treatment early.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Common side effects (occurring in less than 1 in 10 but more than 1 in 100 patients):

- Soft, loose stools or diarrhoea. Please inform your doctor immediately if you have persistent diarrhoea, as this may require a reduction in the dose. If you do suffer from diarrhoea, make sure you drink enough liquids to replace your fluid and salt balance. Diarrhoea may also occur as a result of overdose.

Very rare side effects (occurring in less than 1 in 10,000 patients):

- During the treatment of primary biliary cholangitis: severe right-sided upper abdominal pain, severe worsening of liver scarring - this partially improves 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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 DEOXXA

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 and bottle label after EXP. The expiry date refers to the last day of that month.

Keep the bottle in the outer carton in order to protect from light. Do not freeze.

Opened bottles must be used within 5 months.

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. Recycle the empty packaging where possible.

6. Contents of the pack and other information

What DEOXXA contains

The active substance is ursodeoxycholic acid. Each 5 ml of suspension contains 250 mg of ursodeoxycholic acid.

The other ingredients are benzoic acid (E 210), citric acid, glycerol, microcrystalline cellulose, carmellose sodium, sodium chloride, sodium citrate dihydrate, sodium cyclamate, propylene glycol (E 1520), purified water, xylitol and citrus flavouring (contains propylene glycol (E 1520) and ethanol).

What DEOXXA looks like and contents of the pack

DEOXXA is a white suspension with small air bubbles and a lemon smell supplied in brown plastic (polyethylene terephthalate (PET)) bottles with a polypropylene / polyethylene child-resistant cap. Each bottle contains 250 ml of suspension. The carton also contains a transparent 5 ml plastic (polystyrene) measuring spoon with 4 graduations of 1.25 ml, 2.5 ml, 3.75 ml and 5 ml for dispensing the suspension.

Marketing Authorisation Holder

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Other sources of information:

Further information, help, advice and details of local support groups can be found at:

The PBC Foundation 2 York Place Edinburgh Scotland EH1 3EP Telephone: +44 (0) 131 556 6811 www.pbcfoundation.org.uk	The British Liver Trust 2 Southampton Road Ringwood England BH24 1HY Telephone: +44 (0) 1425 481320 www.britishlivertrust.org.uk
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