

Package leaflet: Information for the user

Ursofalk® 250mg/5ml 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.

What is in this leaflet:

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

1. What Ursofalk suspension is and what it is used for

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

Ursofalk suspension 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 gallstone(s).
- 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 Ursofalk suspension

Do NOT take Ursofalk suspension if

- you are, or have been told you are, allergic (hypersensitive) to bile acids (like ursodeoxycholic acid) or to 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 Ursofalk suspension.

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 Ursofalk 250mg/5ml suspension

The effects of these medicines may be altered:

A **reduction in the effects** of the following medicines is possible when taking Ursofalk suspension:

- 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 Ursofalk.
- 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 Ursofalk suspension:

- 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 Ursofalk for the dissolution of gallstones as they may stimulate the formation of gallstones.

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, even if they are medicines obtainable without a prescription. Treatment with Ursofalk suspension may still be allowed. Your doctor will know what is right for you.

Pregnancy breastfeeding 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 Ursofalk 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 Ursofalk, 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 breastfeeding or about to start breastfeeding.

Driving and using machines:

No particular precautions are necessary.

Ursofalk 250mg/5ml suspension contains benzoic acid, propylene glycol 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 50 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 11 mg sodium 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 Ursofalk suspension

Always take Ursofalk suspension exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Opening the child-resistant closure:

Always shake the closed bottle well before use.

To open the bottle, depress the closure firmly while turning it towards the left.

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

Dosage

During the first 3 months of treatment, Ursofalk suspension 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.

| Body weight (kg) | Daily dose (mg/kg BW) | Cups* of Ursofalk suspension | | | |
|------------------|-----------------------|------------------------------|--------|---------|----------------------|
| | | first 3 months | | | subsequently |
| | | morning | midday | evening | evening (once daily) |
| 8 – 11 | 12 - 16 | – | ¼ | ¼ | ½ |
| 12 – 15 | 12 - 16 | ¼ | ¼ | ¼ | ¾ |

| | | | | | |
|----------|---------|---|---|---|-----|
| 16 – 19 | 13 - 16 | ½ | – | ½ | 1 |
| 20 – 23 | 13 - 15 | ¼ | ½ | ½ | 1 ¼ |
| 24 – 27 | 13 - 16 | ½ | ½ | ½ | 1 ½ |
| 28 – 31 | 14 - 16 | ¼ | ½ | 1 | 1 ¾ |
| 32 – 39 | 12 - 16 | ½ | ½ | 1 | 2 |
| 40 – 47 | 13 - 16 | ½ | 1 | 1 | 2 ½ |
| 48 – 62 | 12 - 16 | 1 | 1 | 1 | 3 |
| 63 – 80 | 12 - 16 | 1 | 1 | 2 | 4 |
| 81 – 95 | 13 - 16 | 1 | 2 | 2 | 5 |
| 96 – 115 | 13 - 16 | 2 | 2 | 2 | 6 |
| over 115 | | 2 | 2 | 3 | 7 |

* One cup (equivalent to 5ml suspension) contains 250mg ursodeoxycholic acid.

How to take Ursofalk suspension

Take Ursofalk suspension regularly.

Duration of treatment

Ursofalk suspension may be continued indefinitely in cases of primary biliary cholangitis.

To dissolve cholesterol gallstones

Dosage

Approximately 10mg per kg body weight (BW) daily, as follows:

| Body weight (kg) | Cups* | Equivalent in ml |
|------------------|-------------|------------------|
| 5 to 7 | ¼ | 1.25 |
| 8 to 12 | ½ | 2.50 |
| 13 to 18 | ¾ (= ¼ + ½) | 3.75 |
| 19 to 25 | 1 | 5.00 |
| 26 to 35 | 1½ | 7.50 |
| 36 to 50 | 2 | 10.00 |
| 51 to 65 | 2½ | 12.50 |
| 66 to 80 | 3 | 15.00 |
| 81 to 100 | 4 | 20.00 |
| over 100 | 5 | 25.00 |

* One cup (equivalent to 5ml suspension) contains 250mg ursodeoxycholic acid.

How to take Ursofalk suspension

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 Ursofalk 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

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.

Single doses for children with a body weight up to 10kg should be given with a syringe as the cup provided does not cover volumes below 1.25ml. Use a single-use 2ml syringe with a graduation of 0.1ml. Please note: Single-use 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 the enclosed cup.
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 in the syringe, adjust if necessary
6. Carefully dispense the syringe contents directly into the child's mouth.

Do not put the syringe into the bottle. Do not put unused suspension from the syringe or the cup back into the bottle.

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

Measuring device: single-use 2ml graduated syringe (not provided)

| Body weight (kg) | Ursofalk 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 cup provided can be used for children over 10kg body weight.

More than 10 kg body weight (BW): Dosing 20-25mg Ursodeoxycholic acid/kg/day

Measuring device: cup

| Body weight (kg) | Daily dose (mg/kg BW) | *Cups of Ursofalk suspension | |
|------------------|-----------------------|------------------------------|---------|
| | | Morning | Evening |

| | | | |
|----------------|-------|----|----|
| 11 – 12 | 21-23 | ½ | ½ |
| 13 – 15 | 21-24 | ½ | ¾ |
| 16 – 18 | 21-23 | ¾ | ¾ |
| 19 – 21 | 21-23 | ¾ | 1 |
| 22 – 23 | 22-23 | 1 | 1 |
| 24 – 26 | 22-23 | 1 | 1¼ |
| 27 – 29 | 22-23 | 1¼ | 1¼ |
| 30 – 32 | 21-23 | 1¼ | 1½ |
| 33 – 35 | 21-23 | 1½ | 1½ |
| 36 – 38 | 21-23 | 1½ | 1¾ |
| 39 – 41 | 21-22 | 1¾ | 1¾ |
| 42 – 47 | 20-22 | 1¾ | 2 |
| 48 – 56 | 20-23 | 2¼ | 2¼ |
| 57 – 68 | 20-24 | 2¾ | 2¾ |
| 69 – 81 | 20-24 | 3¼ | 3¼ |
| 82 – 100 | 20-24 | 4 | 4 |
| >100 | | 4½ | 4½ |

* One cup (equivalent to 5ml suspension) contains 250mg ursodeoxycholic acid.

Conversion table:

| | Ursofalk suspension | Ursodeoxycholic acid |
|-------|---------------------|----------------------|
| 1 cup | ≡ 5ml | ≡ 250mg |
| ¾ cup | ≡ 3.75ml | ≡ 187.5mg |
| ½ cup | ≡ 2.5ml | ≡ 125mg |
| ¼ cup | ≡ 1.25ml | ≡ 62.5mg |

How to take Ursofalk 250mg/5ml suspension

Take Ursofalk suspension two to three times per day, as advised.

Take Ursofalk suspension 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 Ursofalk suspension is too strong or too weak, please talk to your doctor or pharmacist.

If you take more Ursofalk suspension than you should

If you or anyone else takes too much of the suspension, seek immediate medical attention.

If you forget to take Ursofalk suspension

Do not take more oral suspension the next time, but just continue the treatment with the prescribed dose.

If you stop taking Ursofalk suspension

Always speak to your doctor before you decide to interrupt treatment with Ursofalk suspension or to stop your treatment early.

4. Possible side effects

Like all medicines, Ursofalk suspension 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:

Ireland:

HPRA Pharmacovigilance
Website: www.hpra.ie

UK:

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 Ursofalk suspension

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 the bottle after “EXP”. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Opened bottles must be used within 4 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 to protect the environment.

6. Contents of the pack and further information

What Ursofalk suspension contains

The active substance is ursodeoxycholic acid.

5ml suspension (equivalent to 1 cup) contains 250mg ursodeoxycholic acid.

The other ingredients are:

benzoic acid, citric acid, glycerol, microcrystalline cellulose, carmellose sodium, sodium chloride, sodium citrate, sodium cyclamate, propylene glycol, purified water, xylitol and lemon flavouring.

What Ursofalk suspension looks like and contents of the pack

Ursofalk 250mg/5ml suspension is a white liquid with small air bubbles and a lemon odour.

Ursofalk 250mg/5ml suspension is available in the following packs:

Amber glass bottle containing 250 ml suspension with a child-resistant plastic screw cap and a 5 ml measuring cup with 4 embossed graduations: 1.25 ml, 2.5 ml, 3.75 ml and 5 ml.

Marketing Authorisation Holders:

Ireland:

Dr. Falk Pharma GmbH

Leinenweberstrasse 5

79108 Freiburg

Germany

Tel.: + 49 (0) 761 1514-0

Fax: + 49 (0) 761 1514-321

e-mail: zentrale@drfalkpharma.de

UK:

Dr. Falk Pharma UK Ltd

Unit K, Bourne End Business Park

Cores End Road

Bourne End

SL8 5AS

UK

Manufactured by:

Dr. Falk Pharma GmbH

Leinenweberstr. 5

79108 Freiburg

Germany

Tel: +49 (0)761/1514-0

Fax: +49 (0)761/1514-321

E-mail: zentrale@drfalkpharma.de

This leaflet was last revised in August 2020.

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