

Ursofalk® 250mg Capsules

(ursodeoxycholic acid)

Patient Information Leaflet

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.

Your medicine is called Ursofalk 250mg Capsules, throughout this leaflet it will be referred to as Ursofalk Capsules.

In this leaflet:

- 1 What Ursofalk capsules are and what they are used for
- 2 Before you take Ursofalk capsules
- 3 How to take Ursofalk capsules
- 4 Possible side effects
- 5 How to store Ursofalk capsules
- 6 Further information

1 What Ursofalk Capsules are and what they are used for

Ursodeoxycholic acid, the active substance in Ursofalk capsules, is a naturally-occurring bile acid. Small amounts are found in human bile.

Ursofalk capsules are used:

- * 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 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

2 Before you take Ursofalk Capsules

Do NOT take Ursofalk capsules 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 Ursofalk capsules (these are listed in section "6. Further information")
- * your gall bladder does not work properly
- * you have gallstones that are visible on an x-ray
- * you have acute inflammation of the gall bladder or biliary tract
- * you have an obstruction of the biliary tract (blockage of the common bile duct or a cystic duct)
- * you suffer from frequent cramp-like pains in the upper abdomen (biliary colic).
- * you have hardening of the gallstones caused by a build-up of calcium.

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.

Further precautions:

Ursofalk capsules must be used under medical supervision.

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.

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

Taking other medicines with Ursofalk capsules

Please tell your doctor if you are taking or have recently taken any other medicines which contain the following ingredients. The effects of these medicines may be altered (interactions):

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

- * colestyramine, charcoal, 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.

An **increase in the effects** of the following medicines is possible when taking Ursofalk 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.

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 250mg hard capsules 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 any other medicines, even if they are medicines obtainable without a prescription. Treatment with Ursofalk capsules may still be allowed. Your doctor will know what is right for you.

Pregnancy and breastfeeding:

Ask your doctor or pharmacist for advice before taking/using any medicine.

- You should not take Ursofalk 250mg hard capsules during pregnancy unless your doctor thinks it is absolutely necessary. Use of Ursofalk during the first three months of pregnancy may affect the foetus.
- Check that you are not pregnant before taking this medicine.
- Use a reliable method of contraception – non-hormonal contraceptives (barrier methods) or low-oestrogen oral contraceptives are recommended. If you are taking Ursofalk 250mg hard capsules for dissolution of gallstones, only use non-hormonal contraceptives, as hormonal oral contraceptives may stimulate the formation of gallstones.
- Do not take this medicine if you are breastfeeding as the active ingredient in Ursofalk 250mg hard capsules may pass into breast milk. If treatment with Ursofalk 250mg hard capsules is necessary, then stop breastfeeding.

Use in children:

There are no age limits to the use of Ursofalk capsules. The administration of Ursofalk capsules is based on body weight and the medical condition.

Driving and using machines:

No particular precautions are necessary.

3 How to take Ursofalk Capsules

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

To dissolve cholesterol gallstones

Dosage

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

- 50 – 62 kg 2 capsules daily
- 63 – 85 kg 3 capsules daily
- 86 – 120 kg 4 capsules daily

How to take Ursofalk 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.

Ursofalk® 250mg Capsules

(ursodeoxycholic acid)

Patient Information Leaflet (continued)

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.

For primary biliary cirrhosis (chronic inflammation of the bile ducts)

Dosage

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

| Body weight (kg) | Daily dose mg/kg BW | Ursofalk 250mg hard 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 |

Ursofalk suspension is available if you weigh less than 47kg or cannot swallow capsules.

How to take Ursofalk capsules

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

Duration of treatment

Ursofalk capsules may be continued indefinitely in cases of primary biliary cirrhosis.

Note:

In patients with primary biliary cirrhosis, the symptoms may worsen at the start of treatment, e.g. the itching may increase. This only occurs in rare cases. If this happens, therapy can be continued with a lower daily dose of Ursofalk capsules. Each week, your doctor will then gradually increase the daily dose, until you reach the required dose.

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

If you take more Ursofalk capsules than you should:

If you or anyone else take too many of the capsules, seek immediate attention.

If you forget to take Ursofalk capsules:

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

If you stop taking Ursofalk capsules:

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

4 Possible side effects

Like all medicines, Ursofalk capsules can cause side effects, although not everybody gets them.

You should contact your doctor immediately if you experience any of the following symptoms after taking Ursofalk:

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

- soft, loose stools or diarrhoea. 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 cirrhosis: 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)

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 How to store this medicine

- * Keep out of the sight and reach of children.
- * Do not use Ursofalk after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.
- * If your medicine becomes discoloured or shows any other signs of deterioration, consult your pharmacist who will tell you what to do.
- * 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 this medicine contains:

The active ingredient is ursodeoxycholic acid and each capsule contains 250mg of this ingredient.

These capsules also contain corn starch, magnesium stearate, silica, colloidal anhydrous, gelatin, sodium lauryl sulphate, titanium dioxide E171 and purified water.

What this medicine looks like and contents of the pack

Each carton of Ursofalk Capsules are available in a pack size of 100 capsules.

Manufacturer and Licence Holder

This medicine is manufactured by Dr Falk Pharma GmbH, Leinenweberstr. 5, 79108 Freiburg, Germany and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

POM 15184/1274

Ursofalk is a registered trademark of Dr Falk Pharma GmbH.

Revision date: 21/11/12

Blind or partially sighted?

Is this leaflet hard to see or read?

Phone Lexon (UK) Limited, Tel: 01527 505414 for help.

You may also wish to contact the following national organisation which offers help, advice and local support groups:
Primary Biliary Cirrhosis Foundation, 54 Queen Street, Edinburgh, EH2 3NS.
Telephone: 0131 225 8586.

Ursodeoxycholic Acid 250mg Capsules

Patient Information Leaflet

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- * 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.

Your medicine is called Ursodeoxycholic Acid 250mg Capsules, throughout this leaflet it will be referred to as Ursodeoxycholic Acid Capsules.

In this leaflet:

- 1 What Ursodeoxycholic Acid Capsules are and what they are used for
- 2 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 Further information

1 What Ursodeoxycholic Acid Capsules are and what they are used for

Ursodeoxycholic acid, the active substance in Ursodeoxycholic Acid Capsules, is a naturally-occurring bile acid. Small amounts are found in human bile.

Ursodeoxycholic Acid Capsules are used:

- * to dissolve gallstones caused by excess cholesterol in the gall bladder. where the gallstones are not be 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 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

2 Before you take Ursodeoxycholic Acid Capsules

Do NOT take Ursodeoxycholic Acid Capsules 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 Ursodeoxycholic Acid Capsules (these are listed in section "6. Further information")
- * your gall bladder does not work properly
- * you have gallstones that are visible on an x-ray
- * you have acute inflammation of the gall bladder or biliary tract
- * you have an obstruction of the biliary tract (blockage of the common bile duct or a cystic duct)
- * you suffer from frequent cramp-like pains in the upper abdomen (biliary colic).
- * you have hardening of the gallstones caused by a build-up of calcium.

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.

Further precautions:

Ursodeoxycholic Acid Capsules must be used under medical supervision.

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.

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

Taking other medicines with Ursodeoxycholic Acid Capsules

Please tell your doctor if you are taking or have recently taken any other medicines which contain the following ingredients. The effects of these medicines may be altered (interactions):

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

- * colestyramine, charcoal, 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.
- * 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.

An **increase 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.

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.

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

Pregnancy and breastfeeding:

Ask your doctor or pharmacist for advice before taking/using any medicine.

- * You should not take Ursodeoxycholic Acid capsules during pregnancy unless your doctor thinks it is absolutely necessary. Use of Ursodeoxycholic Acid during the first three months of pregnancy may affect the foetus.
- * Check that you are not pregnant before taking this medicine.
- * Use a reliable method of contraception – non-hormonal contraceptives (barrier methods) or low-oestrogen oral contraceptives are recommended. If you are taking Ursodeoxycholic Acid capsules for dissolution of gallstones, only use non-hormonal contraceptives, as hormonal oral contraceptives may stimulate the formation of gallstones.
- * Do not take this medicine if you are breastfeeding as the active ingredient in Ursodeoxycholic Acid capsules may pass into breast milk. If treatment with Ursodeoxycholic Acid capsules is necessary, then stop breastfeeding.

Use in children:

There are no age limits to the use of Ursodeoxycholic Acid Capsules. The administration of Ursodeoxycholic Acid Capsules is based on body weight and the medical condition.

Driving and using machines:

No particular precautions are necessary.

3 How to take Ursodeoxycholic Acid Capsules

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

To dissolve cholesterol gallstones

Dosage

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

- 50 – 62 kg 2 capsules daily
- 63 – 85 kg 3 capsules daily
- 86 – 120 kg 4 capsules daily

Ursodeoxycholic Acid 250mg Capsules

Patient Information Leaflet (continued)

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 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.

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 tests improve, the total daily dose may be taken once a day in the evening.

| Body weight (kg) | Daily dose mg/kg BW | Ursodeoxycholic Acid 250mg Capsules | | | |
|------------------|---------------------|-------------------------------------|--------|---------|----------------------|
| | | first 3 months | | | subsequently |
| | | morning | midday | evening | evening (once daily) |
| 47 – 62 | 12 - 16 | 1 | 1 | 1 | 3 |
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Ursodeoxycholic Acid suspension is available if you weigh less than 47kg or cannot swallow capsules.

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 primary biliary cirrhosis.

Note:

In patients with primary biliary cirrhosis, the symptoms may worsen at the start of treatment, e.g. the itching may increase. This only occurs in rare cases. If this happens, therapy can be continued with a lower daily dose of Ursodeoxycholic Acid Capsules. Each week, your doctor will then gradually increase the daily dose, until you reach the required dose.

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 Capsules than you should:

If you or anyone else take too many of the capsules, seek immediate medical attention.

If you forget to take Ursodeoxycholic Acid Capsules:

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

If you stop taking Ursodeoxycholic Acid Capsules:

Always speak to your doctor before you decide to interrupt treatment with Ursodeoxycholic Acid Capsules or to stop your treatment early.

4 Possible side effects

Like all medicines, Ursodeoxycholic Acid capsules can cause side effects, although not everybody gets them.

You should contact your doctor immediately if you experience any of the following symptoms after taking Ursodeoxycholic Acid Capsules:

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

- soft, loose stools or diarrhoea. 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 cirrhosis: severe right-sided upper abdominal pain, severe worsening of liver scarring - this partially improves after treatment is stopped.
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- nettle rash (urticaria)

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 How to store this medicine

- * Keep out of the sight and reach of children.
- * Do not use Ursodeoxycholic Acid after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.
- * If your medicine becomes discoloured or shows any other signs of deterioration, consult your pharmacist who will tell you what to do.
- * 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 this medicine contains:

The active ingredient is ursodeoxycholic acid and each capsule contains 250mg of this ingredient.

These capsules also contain corn starch, magnesium stearate, silica, colloidal anhydrous, gelatin, sodium lauryl sulphate, titanium dioxide E171 and purified water.

What this medicine looks like and contents of the pack

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Manufacturer and Licence Holder

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