

# Ursofalk® 250mg Capsules

(ursodeoxycholic acid)

## Patient Information Leaflet

**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 side effects not listed in this leaflet, see section 4.

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

### What is in this leaflet:

- 1 What Ursofalk Capsules are and what they are used for
- 2 What you need to know before you take Ursofalk Capsules
- 3 How to take Ursofalk Capsules
- 4 Possible side effects
- 5 How to store Ursofalk Capsules
- 6 Contents of the pack and further information

## 1 What Ursofalk Capsules are and what they are used for

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

### Ursofalk 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 Ursofalk Capsules

### Do NOT take Ursofalk Capsules if

- you are, or have been told you are, allergic (hypersensitive) to bile acids like UDCA or to any of the other ingredients of Ursofalk capsules (listed in section 6).
- your gall bladder does not work properly.
- your doctor has said you have calcified gallstones (they are visible on an x-ray).
- you have an 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 pains in the upper abdomen (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 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 Ursofalk Capsules

The effects of these medicines may be altered:

A **reduction in the effects** of the following medicines is possible when taking Ursofalk 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 Ursofalk Capsules.
- 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 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)

If you are taking Ursofalk capsules for the dissolution of gallstones, please inform your doctor, in case you are taking any medicines that contain oestrogenic hormones or blood cholesterol lowering agents such as clofibrate. These medicines stimulate the formation of gallstones, which is a counter-effect to the treatment with Ursofalk.

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 Capsules may still be allowed. Your doctor will know what is right for you.

**Pregnancy, breastfeeding and fertility:** If you are pregnant or breastfeeding, 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 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 Ursofalk, your doctor will check that you are not pregnant and review your contraceptive method to make sure it is appropriate.

**Breastfeeding:** Tell your doctor if you are breastfeeding or about to start breastfeeding.

### 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. Ursofalk suspension is available if a lower dose is needed or you cannot swallow capsules.

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

### 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 PBC.

| Body weight<br>BW (kg) | Daily dose<br>(mg/kg BW) | Ursofalk 250mg hard capsules |        |         |                         |
|------------------------|--------------------------|------------------------------|--------|---------|-------------------------|
|                        |                          | First 3 months               |        |         | Subsequently            |
|                        |                          | Morning                      | Midday | Evening | Evening<br>(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                       |

### 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

# Ursofalk® 250mg Capsules

(ursodeoxycholic acid)

## Patient Information Leaflet (continued)

### 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.

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

| Body weight BW (kg) | Daily dose (mg/kg BW) | Ursofalk 250mg hard 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 Ursofalk 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 Ursofalk Capsules is too strong or too weak, please talk to your doctor or pharmacist.

#### If you take more Ursofalk Capsules 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 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 talk to your doctor before you decide to interrupt treatment with Ursofalk capsules or decide to stop your treatment early.

## 4 Possible side effects

Like all medicines, Ursofalk Capsules 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.

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

- 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 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](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 this medicine

- \* Keep out of the sight and reach of children.
- \* Do not use Ursofalk Capsules 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 Contents of the pack and 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: 12/04/17

Blind or partially sighted?

Is this leaflet hard to see or read?

Phone Lexon (UK) Limited,

Tel: 01527 505414 to obtain the leaflet

in a format suitable for you

### 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](http://www.pbcfoundation.org.uk)

The British Liver Trust

2 Southampton Road

Ringwood

England

BH24 1HY

Telephone: +44 (0) 1425 481320

[www.britishlivertrust.org.uk](http://www.britishlivertrust.org.uk)

# Ursodeoxycholic Acid 250mg Capsules

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

### What is in this leaflet:

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- 2 What you need to know before you take Ursodeoxycholic Capsules
- 3 How to take Ursodeoxycholic Capsules
- 4 Possible side effects
- 5 How to store Ursodeoxycholic Capsules
- 6 Contents of the pack and further information

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

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

### Ursodeoxycholic 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 Ursofalk Capsules

### Do NOT take Ursodeoxycholic Capsules if

- you are, or have been told you are, allergic (hypersensitive) to bile acids like UDCA or to any of the other ingredients of Ursodeoxycholic Capsules (listed in section 6).
- your gall bladder does not work properly.
- your doctor has said you have calcified gallstones (they are visible on an x-ray).
- you have an 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 pains in the upper abdomen (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 Ursodeoxycholic 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 Capsules

The effects of these medicines may be altered:

A **reduction in the effects** of the following medicines is possible when taking Ursodeoxycholic 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 Capsules.
- 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 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)

If you are taking Ursodeoxycholic Capsules for the dissolution of gallstones, please inform your doctor, in case you are taking any medicines that contain oestrogenic hormones or blood cholesterol lowering agents such as clofibrate. These medicines stimulate the formation of gallstones, which is a counter-effect to the treatment with Ursofalk.

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 Ursodeoxycholic Capsules may still be allowed. Your doctor will know what is right for you.

**Pregnancy, breastfeeding and fertility:** If you are pregnant or breastfeeding, 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 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 Ursofalk, your doctor will check that you are not pregnant and review your contraceptive method to make sure it is appropriate.

**Breastfeeding:** Tell your doctor if you are breastfeeding or about to start breastfeeding.

### Driving and using machines:

No particular precautions are necessary.

## 3 How to take Ursodeoxycholic Capsules

Always take Ursodeoxycholic Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Ursofalk suspension is available if a lower dose is needed or you cannot swallow capsules.

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

#### Dosage

During the first 3 months of treatment, you should take Ursodeoxycholic 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.

#### How to take Ursodeoxycholic Capsules

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

#### Duration of treatment

| Body weight<br>BW (kg) | Daily dose<br>(mg/kg BW) | Ursodeoxycholic 250mg hard capsules |        |         |                         |
|------------------------|--------------------------|-------------------------------------|--------|---------|-------------------------|
|                        |                          | First 3 months                      |        |         | Subsequently            |
|                        |                          | Morning                             | Midday | Evening | Evening<br>(once daily) |
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| 94 – 109               | 14 – 16                  | 2                                   | 2      | 2       | 6                       |
| over 110               |                          | 2                                   | 2      | 3       | 7                       |

Ursodeoxycholic Capsules may be continued indefinitely in cases of PBC.

#### 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

## Patient Information Leaflet (continued)

### How to take Ursodeoxycholic 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.

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

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| 100-109             | 23-25                 | 3                            | 3      | 4       |
| >110                |                       | 3                            | 4      | 4       |

### How to take Ursodeoxycholic 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 Capsules is too strong or too weak, please talk to your doctor or pharmacist.

#### If you take more Ursodeoxycholic Capsules 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 Capsules:

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

#### If you stop taking Ursodeoxycholic Capsules:

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

## 4 Possible side effects

Like all medicines, Ursodeoxycholic Capsules 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.

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- 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

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## 5 How to store this medicine

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- \* 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 Contents of the pack and 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 Ursodeoxycholic 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

Ursosalk is a registered trademark of Dr Falk Pharma GmbH.

Revision date: 12/04/17

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## Is this leaflet hard to see or read?

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## Tel: 01527 505414 to obtain the leaflet

## in a format suitable for you

### Other sources of information:

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The PBC Foundation

2 York Place

Edinburgh

Scotland

EH1 3EP

Telephone: +44 (0) 131 556 6811

[www.pbcfoundation.org.uk](http://www.pbcfoundation.org.uk)

The British Liver Trust

2 Southampton Road

Ringwood

England

BH24 1HY

Telephone: +44 (0) 1425 481320

[www.britishlivertrust.org.uk](http://www.britishlivertrust.org.uk)