

Package leaflet: Information for the user

Ursofalk® 250mg capsules (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 name of your medicine is Ursofalk 250mg capsules but will be referred to as Ursofalk capsules throughout in this leaflet.

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 other 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 cholangitis (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 15mm 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.

- 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)

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 capsules for the dissolution of gallstones, as they may stimulate the formation of gallstones.

Tell your doctor or pharmacist if you are taking, 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 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 cholangitis (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.

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

To dissolve cholesterol gallstones

Dosage

Approximately 10mg per kg body weight (BW) daily, as follows:
50-62kg 2 capsules daily
63-85kg 3 capsules daily
86-120kg 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.

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 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] | Ursofalk 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: 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)

Not known: frequency cannot be estimated from the available data

- itching
- feeling sick, vomiting

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 the Yellow Card Scheme at: 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

Keep out of the sight and reach of children.

There are no special storage conditions.

Do not take the capsules after the expiry date which is stated on the carton and blister labels after 'Exp'. The expiry date refers to the last day of that month.'

If the capsule becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.

Remember if your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal.

Only keep this medicine if your doctor tells you to.

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 other Information

What Ursofalk contains:

The active ingredient in the Ursofalk is ursodeoxycholic acid.

Each capsule contains 250mg ursodeoxycholic acid.

The other ingredients are maize starch, colloidal anhydrous silica, magnesium stearate, gelatin, sodium lauryl sulphate, purified water and titanium dioxide (E171).

What Ursofalk looks like and contents of the pack

The hard gelatin capsules have an unmarked white body and cap and contain a white powder.

Ursofalk capsules are available as blister packs of 50 and 100 capsules.

Manufactured by: Dr. Falk Pharma GmbH, Leinenweberstr. 5, 79108, Freiburg, Germany.

Procured from within the EU and repackaged by the Product

Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

POM

Ursofalk® 250mg capsules: PL 18799/2757

Leaflet date: 29.04.2025

Ursofalk is a registered trademark of Dr. Falk Pharma GmbH.

**Blind or partially sighted?
Is this leaflet hard to see or read?
Call 0208 515 3763 to obtain the
leaflet in a format suitable for you.**

Package leaflet: Information for the user

Ursodeoxycholic acid 250mg capsules

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 name of your medicine is Ursodeoxycholic acid 250mg capsules but will be referred to as Ursodeoxycholic acid capsules throughout in this leaflet.

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 (UDCA), 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:

- 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 cholangitis (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 15mm 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, or have been told you are, allergic (hypersensitive) to bile acids like UDCA or to any of the other ingredients of Ursodeoxycholic acid 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 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

The effects of these medicines may be altered:

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 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 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.

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

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 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.

Ursodeoxycholic acid capsules suspension is available if a lower dose is needed or you cannot swallow capsules.

For primary biliary cholangitis (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 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.

To dissolve cholesterol gallstones

Dosage

Approximately 10mg per kg body weight (BW) daily, as follows:
50-62kg 2 capsules daily
63-85kg 3 capsules daily
86-120kg 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 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 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 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 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 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 talk to your doctor before you decide to interrupt treatment with Ursodeoxycholic acid capsules or decide to stop your treatment early.

4. Possible side effects

Like all medicines, Ursodeoxycholic acid capsules 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)

Not known: frequency cannot be estimated from the available data

- itching
- feeling sick, vomiting

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 the Yellow Card Scheme at: 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 Ursodeoxycholic acid capsules

Keep out of the sight and reach of children.

There are no special storage conditions.

Do not take the capsules after the expiry date which is stated on the carton and blister labels after 'Exp'. The expiry date refers to the last day of that month.'

If the capsule becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.

Remember if your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal.

Only keep this medicine if your doctor tells you to.

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 Ursodeoxycholic acid capsules contains:

The active ingredient in the Ursodeoxycholic acid is ursodeoxycholic acid.

Each capsule contains 250mg ursodeoxycholic acid.

The other ingredients are maize starch, colloidal anhydrous silica, magnesium stearate, gelatin, sodium lauryl sulphate, purified water and titanium dioxide (E171).

What Ursodeoxycholic acid capsules looks like and contents of the pack

The hard gelatin capsules have an unmarked white body and cap and contain a white powder.

Ursodeoxycholic acid capsules are available as blister packs of 50 and 100 capsules.

Manufactured by: Dr. Falk Pharma GmbH, Leinenweberstr. 5, 79108, Freiburg, Germany.

Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

POM

Ursodeoxycholic acid 250mg capsules: PL 18799/2757

Leaflet date: 29.04.2025

Blind or partially sighted?
Is this leaflet hard to see or read?
Call **0208 515 3763** to obtain the leaflet in a format suitable for you.