

Package leaflet: Information for the user

Ursodeoxycholic acid Orion 250 mg hard 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Ursodeoxycholic acid Orion is and what it is used for

Ursodeoxycholic acid Orion contains the active substance ursodeoxycholic acid which is a naturally occurring bile acid which is found in small amounts in human bile.

Ursodeoxycholic acid Orion is used to dissolve small gallstones and for the treatment of a liver disease (primary biliary cirrhosis) by e.g. stimulating bile flow.

In children aged 6 to 18 years Ursodeoxycholic acid Orion is used to treat liver-bile disorders associated with cystic fibrosis.

2. What you need to know before you take Ursodeoxycholic acid Orion

Do not take Ursodeoxycholic acid Orion

- if you are allergic to ursodeoxycholic acid, other bile acids or any of the other ingredients of this medicine (listed in section 6)
- if you have acute inflammation of the gall bladder or the biliary tract
- if you have a blockage of the common bile duct or cystic duct
- if you often have biliary colic (cramp-like upper abdomen pain)
- if your doctor has told you that you have calcified gallstones
- if you have impaired function of the gall bladder
- if your child has impaired bile flow (biliary atresia).

Please ask your doctor about the conditions mentioned above. You should also ask if you have previously had any of these conditions.

Warnings and precautions

During the first three months of treatment the function of your liver will be tested in order to evaluate the effect of the treatment and in order to detect possible side effects in the liver.

Women taking Ursodeoxycholic acid Orion in order to dissolve gallstones should only use non-hormonal contraceptives as hormonal contraceptives might induce formation of gallstones (also see section on pregnancy and breast-feeding below).

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

Please inform your doctor if you have diarrhoea, as this may require a change in the dose.

Other medicines and Ursodeoxycholic acid Orion

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

This is especially important for the following medicines:

- colestipol and colestyramin (used to lower blood lipids)
 - antacids (used to treat heartburn) containing aluminium hydroxide or aluminium oxide
- Should the use of a medicinal product containing one of these substances mentioned above be necessary, it must be taken at least 2 hours before or after Ursodeoxycholic acid Orion.
- ciclosporin (reduces the activity of the immune system at transplantation)
 - ciprofloxacin (used to treat infections)
 - nitrendipin (used to treat high blood pressure)
 - dapsone (used to treat HIV)
 - oestrogenic hormones (in certain oral contraceptives and medicines used for menopause)
 - clofibrate (used to lower blood lipids)
 - rosuvastatin (used to lower blood lipids).

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Before start of treatment with Ursodeoxycholic acid Orion it will be checked that you are not pregnant.

Ursodeoxycholic acid Orion should not be used during pregnancy unless clearly necessary. Women of child-bearing potential should only be treated with Ursodeoxycholic acid Orion if a contraceptive is used concomitantly. Non-hormonal contraceptives or low dose oestrogen oral contraceptives is recommended.

Only use non-hormonal contraceptives if you use Ursodeoxycholic acid Orion to dissolve gallstones as hormonal contraceptives might induce the formation of gallstones.

It is not known if Ursodeoxycholic acid Orion passes into breast milk. Therefore consult your doctor before use if you are breast-feeding.

Driving and using machines

There is no known effect on the ability to drive or use machines.

3. How to take Ursodeoxycholic acid Orion

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The capsules should be swallowed whole with sufficient liquid. If due to the size of the capsule, the patient has difficulty swallowing, the capsule may, if necessary, be opened and the contents added to yoghurt, for example.

Dissolution of gallstones:

The recommended dose in adults is 10–12 mg/kg body weight daily, divided in 2 doses during the day. It generally takes 6–24 months to dissolve gallstones. If there is no reduction in the size of the gallstones after 12 months, treatment should be stopped.

6 to 10 months after onset of treatment your doctor will test if the treatment is successful.

Primary biliary cirrhosis:

The recommended dose in adults is 12–16 mg/kg body weight daily.

During the first 3 months of treatment, Ursodeoxycholic acid Orion should be taken in divided doses during the day. As liver function tests improve, the total daily dose may be taken once a day, preferably in the evening.

The use of Ursodeoxycholic acid Orion can be continued indefinitely in cases of primary biliary cirrhosis.

Use in children and adolescents

Children with cystic fibrosis aged 6 years to less than 18 years:

The recommended dose is 20 mg/kg/day in 2–3 divided doses, with a further increase to 30 mg/kg/day if necessary.

If you take more Ursodeoxycholic acid Orion than you should

Diarrhoea may occur as a result of overdose. Contact your doctor immediately if you have persistent diarrhoea.

If you forget to take Ursodeoxycholic acid Orion

Do not take a double dose to make up for a forgotten dose, continue treatment as prescribed.

If you stop taking Ursodeoxycholic acid Orion

Always consult your doctor before you stop taking Ursodeoxycholic acid Orion.

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

4. Possible side effects

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

Common (may affect up to 1 in 10 people)

- diarrhoea, pale stools.

Very rare (may affect up to 1 in 10,000 people)

- severe right-sided upper abdominal pain during the treatment of primary biliary cirrhosis
- worsening of reduced liver function during the treatment of primary biliary cirrhosis which partially regresses after treatment is discontinued
- calcification of gallstones
- nettle rash.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system](#) listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ursodeoxycholic acid Orion

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

Do not store above 30 °C. Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ursodeoxycholic acid Orion contains

- The active substance is ursodeoxycholic acid. One hard capsule contains 250 mg ursodeoxycholic acid.
- The other ingredients are
Capsule content: maize starch, colloidal hydrated silica, magnesium stearate.
Capsule shell: titanium dioxide (E171), gelatin.

What Ursodeoxycholic acid Orion looks like and contents of the pack

White hard gelatin capsule, approximately 21.7 mm x 7.64 mm in size, containing white or almost white powder.

PVC/aluminium blister: 25, 50, 75 and 100 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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