

Ursodeoxycholic Acid 150 mg tablets



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

1. What Ursodeoxycholic Acid is and what it is used for

Ursodeoxycholic Acid contains the active substance ursodeoxycholic acid, which is one of a group of medicines used to dissolve gallstones. Not all gallstones are suitable for treatment with Ursodeoxycholic Acid but your doctor has decided that your condition may be treated this way.

Ursodeoxycholic acid is a chemical present naturally in the body and it helps to control the amount of cholesterol in the blood. Ursodeoxycholic Acid tablets help dissolve gallstones that are made mainly of cholesterol.

2. What you need to know before you take Ursodeoxycholic Acid

Do not take Ursodeoxycholic Acid:

- if you are allergic to ursodeoxycholic acid other bile acids or to any of the other ingredients of this medicine (listed in section 6).
- if you have acute inflammation of the gall bladder or biliary tract
- if you have a blockage of the biliary tract
- if you have frequent episodes of biliary colic (recurrent pain in the upper abdomen)
- if your doctor has told you that you have gallstones which are radio-opaque
- if your gall bladder does not work properly
- if you have inflammatory bowel disease
- if you have a liver or intestinal condition which interferes with the circulation of bile substances e.g. blockage of the bile duct, removal of part of the small bowel.

- if you have any liver disease
- if you have a stomach or duodenal ulcer

Do not take this medicine if any of the above applies to you.

If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Other medicines and Ursodeoxycholic Acid

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

You should tell your doctor if you are taking:

- hormone replacement therapy or the contraceptive pill,
- colestyramine, colestipol or clofibrate (which are medicines to lower blood cholesterol),
- antacids (which are medicines to relieve indigestion or heartburn),
- ciclosporin (an immunosuppressant).
- activated charcoal for indigestion, wind and heartburn
- ciprofloxacin and dapsone (antibacterials used to treat infections)
- nifedipine (used to treat high blood pressure).

Taking Ursodeoxycholic Acid with food and drink

Ursodeoxycholic Acid should be taken after meals, with one dose always being taken after the evening meal.

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 for advice before taking this medicine.

- Ursodeoxycholic Acid should not be taken during pregnancy unless recommended by your doctor.
- Women should use adequate contraception during treatment with Ursodeoxycholic Acid. Contraception should either be non-hormonal e.g. barrier methods or a low oestrogen contraceptive pill. Other oral contraceptive pills should not be taken with Ursodeoxycholic Acid. Ask your doctor or pharmacist for advice.

Do not take Ursodeoxycholic Acid whilst breast-feeding.

Driving and using machines

Ursodeoxycholic Acid should not affect your ability to drive or use machines.

Important information about some of the ingredients of Ursodeoxycholic Acid

This product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Ursodeoxycholic Acid

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

- The usual dose is between 3 and 4 tablets a day. The dose is usually divided up and taken twice a day, i.e. 1 or 2 tablets taken with water after meals. One of the doses should always be taken after your evening meal
- Ursodeoxycholic Acid will work best if taken together with a low cholesterol and calorie controlled diet. You should discuss this with your doctor. You will not normally take Ursodeoxycholic Acid for more than 2 years. Your doctor will give you regular check-ups.

If you take more Ursodeoxycholic Acid than you should:

You should tell your doctor if you have taken more Ursodeoxycholic Acid than you should. It is unlikely that you will notice any problems but you may experience diarrhoea.

If you forget to take Ursodeoxycholic Acid:

- **Do not** worry, take them as soon as you remember. If it is nearly time for the next dose then take only that dose.
- **Do not** take a double dose to make up for a forgotten dose.

If you stop taking Ursodeoxycholic Acid tablets

even for a short amount of time, it may cause the gall stones to come back. Do not stop taking Ursodeoxycholic Acid until you are advised by your doctor.

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

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 and pasty stools

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

- Hives (a raised, itchy rash)
- Gallstone calcification (a process in which the mineral calcium builds up in tissue causing it to harden)

frequency not known (frequency cannot be estimated from the available data)

- Feeling (nausea) or being sick (vomiting)
- Itching

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

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is printed or embossed on the carton and blister after EXP. The expiry date refers to the last day of the month.

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 contains:

The active substance is ursodeoxycholic acid. Each tablet contains 150 mg ursodeoxycholic acid.

The other ingredients are lactose monohydrate, pregelatinised maize starch, sodium starch glycolate, talc and magnesium stearate.

What Ursodeoxycholic Acid looks like and contents of the pack:

Ursodeoxycholic Acid 150mg tablets are white, round tablets, 11 mm diameter with a break line. The tablets are also marked on one side with 'URS 150'.

Ursodeoxycholic Acid 150mg tablets are available in blisters of 60 tablets.

Marketing authorisation holder:

Teva UK Limited
Ridings Point
Whistler Drive
Castleford
WF10 5HX
United Kingdom

Manufacturer:

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This leaflet was last revised in April 2025.

PL 00289/2252