

URSOSAN FORTE[®], 500 mg film-coated tablets

Ursodeoxycholic Acid (500 mg)

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What Ursosan Forte[®] is used for

Ursosan Forte[®] is indicated for:

- dissolution of cholesterol gallstones in the gallbladder. The gallstones must not show as shadows on X-ray images and should not exceed 15 mm in diameter. Gall bladder must be functioning, despite the gallstones.
- symptomatic treatment of primary biliary cirrhosis (PBC), in patients without decompensated hepatic cirrhosis.

How Ursosan Forte[®] works

Ursodeoxycholic acid (UDCA) is found in small amounts in human bile.

Upon oral administration, it induces a decline in cholesterol saturation of the gallbladder through blocking of cholesterol resorption in the intestine and decline in cholesterol secretion to the gall. A gradual decomposition of cholesterol gallstones is presumably achieved through dispersion of cholesterol and forming of liquid crystals.

Before you use Ursosan Forte[®]

- When you must not use it

Do not take Ursosan Forte[®] if

- you are, or have been told you are, allergic (hypersensitive) to bile acids like UDCA or to any

of the other ingredients of this product.

- you have an acute inflammation of the gallbladder 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).
- your doctor has said you have calcified gallstones (they are visible on an x-ray).
- your gallbladder does not work properly.

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.

- Before you start to use it

Pregnancy and breast-feeding

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.

Ursosan Forte[®] must not be used during pregnancy unless clearly necessary.

- Taking other medicines

The effects of these medicines may be altered:

A **reduction in the effects** of Ursosan Forte[®] is possible when taking it with the following medicines:

- cholestyramine, colestipol (used to lower blood lipid levels) or antacids containing aluminium hydroxide or smectite (aluminium oxide) (used to bind stomach acid): If you must take medication that contains any of these substances, it must be taken at least two hours before or after Ursosan Forte[®].

A **reduction in the effects** of the following medicines is possible when taking Ursosan Forte[®]:

- ciprofloxacin and dapson (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 Ursosan Forte[®]:

- 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 Ursosan Forte[®] 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 Ursosan Forte[®].

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 Ursosan Forte[®] may still be allowed. Your doctor will know what is right for you.

How to use Ursosan Forte[®]

- How much to use

For dissolution of cholesterol gallstones, the recommended dose in adult patients is dependent on the body weight (10 mg/kg/day).

For the symptomatic treatment of primary biliary cirrhosis (PBC), the daily dose depends on the body

weight and usually is 10-15 mg/kg/day.

Ursosan Forte® needs to be taken regularly.

Talk to your doctor or pharmacist before taking Ursosan Forte®. Your doctor will know what is right for you.

- How long to use it

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.

- If you forget to use it

If you forget to take Ursosan Forte®, continue at your regular dosing schedule. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

Diarrhoea may occur in overdose with UDCA. In this case, the dose must be reduced, and if diarrhoea persists, the treatment must be discontinued. 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.

While you are using it

- Things you must do

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

- Things you must not do

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.

- Things to be careful of

Talk to your doctor or pharmacist before taking Ursosan Forte®.

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 months 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.

Side effects

Like all medicines, Ursosan Forte® can cause side effects, although not everybody gets them.

Common side effects:

- soft, loose stools or diarrhoea.

Very rare side effects:

- 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).

Effects on ability to drive and use machines

Ursodeoxycholic acid has no or negligible influence on the ability to drive and use machines.

Storage and Disposal of Ursosan Forte®

- Storage

Store at temperatures not exceeding 30 °C.

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 and blister after "Expiry

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

- Disposal

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.

Product Description

- What it looks like

Film-coated tablets.

Almost white, oblong film-coated tablets with a break line and length 17 mm. The tablet can be divided into equal halves.

- Ingredients

- Active Ingredient:

Ursodeoxycholic Acid.

- Inactive Ingredient:

Maize starch, pregelatinised starch, sodium starch glycolate A, silica colloidal anhydrous, magnesium stearate, hypromellose 6, titanium dioxide (E171), macrogol 400.

Manufacturer

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