PACKAGE LEAFLET: INFORMATION FOR THE USER
Ursodeoxycholic Acid 300mg 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.

The name of your medicine is Ursodeoxycholic Acid 300mg tablets but will be referred to as Ursodeoxycholic Acid throughout this leaflet. Please note that this leaflet also contains information about other strength such as Ursodeoxycholic Acid 150mg tablets and Ursodeoxycholic Acid 450mg tablets.

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 Tablets
3. How to take Ursodeoxycholic Acid Tablets
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1. What Ursodeoxycholic Acid is and what it is used for

Ursodeoxycholic Acid influences the composition of the bile, by which cholesterol gallstones can be solved. The effects of Ursodeoxycholic Acid in primary biliary cholangitis and cystic fibrosis can be explained by various mechanisms, such as a protective effect on the liver cells and an effect on the immune system.

1. Ursodeoxycholic Acid Tablets is used in patients:
- with small gallstones
- who do not want to undergo surgery or are not eligible for gallstone surgery
- in whom too much cholesterol has been found in the bile

2. Ursodeoxycholic Acid Tablets is used in patients with primary biliary cholangitis. Primary biliary cholangitis is a disease in which liver tissue is damaged by an impaired drainage of the bile.
3. Ursodeoxycholic Acid Tablets is used in children aged 6 years to 18 years old with liver and biliary diseases caused by cystic fibrosis. Cystic fibrosis, also referred to as mucoviscidosis, is an inherited disorder in which the mucus is particularly tough in the whole body. This may cause, among other conditions, clogging and inflammation in the liver and in the bile ducts.

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

Do not take Ursodeoxycholic Acid Tablets if:
- You have an acute inflammation of the gallbladder or the bile ducts.
- You have a narrowing or blockage of the bile ducts.
- You suffer from often occurring cramp-like pain in the upper abdomen (biliary colic).
- You have calcified gallstones that do not transmit X-rays.
- You have a gall bladder that cannot properly constrict any more.
- You are allergic to bile acids or any of the other ingredients of this medicine (listed in section 6).
- You have an active gastric or duodenal ulcer.

Children
In children with disrupted biliary drainage due to production of connective tissue in the bile duct (biliary atresia) in whom the bile flow is not restored by healing or by an artificial bile duct (portoenterostomy).

Warnings and precautions
This medicine must be used under medical supervision.
Your doctor should examine your liver every 4 weeks during the first three months of treatment. Then this should be done every 3 months. Apart from allowing for identification of responders and non-responders in patients being treated for primary biliary cholangitis, this monitoring would also enable an early detection of potential hepatic deterioration, particularly in patients with advanced primary biliary cholangitis.

When used for dissolving gallstones:
In order to be able to assess the therapeutic progression of the dissolution of gallstones and to timely identify a possible calcification of the stones, the gall bladder, depending on the size of the stones, should be visualized 6 to 10 months after the start of the treatment (oral cholecystography) with total image and occlusions and in the standing and lying position (ultrasound control).

If the gallbladder cannot be visualized on X-rays, or in cases of calcified gallstones, impaired contractility of the gall bladder or frequent episodes of biliary colic, the treatment with Ursodeoxycholic Acid Tablets should be discontinued.

When used for the treatment of advanced primary biliary cholangitis:
In very rare cases decompensation of liver cirrhosis is observed which partially decreased after treatment discontinuation.

Women who use Ursodeoxycholic Acid for dissolving gallstones should stop using the birth control pill and other methods used to prevent pregnancy, because the hormones in the birth control pill can promote the production of gallstones.

When you are in the final stage of primary biliary cholangitis it can in very rare cases occur that your liver function is strongly reduced. The liver function will partly recover after stopping the treatment.

If you experience problems with diarrhoea, your doctor will reduce the dose. If the diarrhoea persists, your doctor may decide to stop the treatment.

Contact your doctor or pharmacist before you start to use this medicine.

Other medicines and Ursodeoxycholic Acid Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This also applies for medicines obtained without a prescription.

The effect of the following drugs can be influenced (interactions):
A **reduced effect** of the following medicines is possible when using this medicine:
- Medicines binding stomach acid based on aluminium hydroxide and bile acid binding substances (colestyramine, colestipol) can bind the ursodeoxycholic acid and thereby prevent its absorption. Therefore, these medicines may not be taken simultaneously with Ursodeoxycholic Acid, but always 2 hours before or after.
- Ursodeoxycholic acid can reduce the absorption of ciprofloxacin, dapsone (antibiotics) and nitrendipine (antihypertensive agent) from the intestine. When one of these resources has been used simultaneously with Ursodeoxycholic Acid Tablets, your doctor will carefully supervise you.

An **intensified effect** of the following medicines is possible when using this medicine:
- Ursodeoxycholic acid may increase the absorption of cyclosporine from the intestine: if necessary, the dosing guided by the cyclosporine concentration should be adjusted in the blood.

Oestrogens, oral contraceptives (‘the pill’) and cholesterol-lowering agents (such as clofibrate) may promote the forming of gallstones, and can thus counteract the effect of the treatment of gallstones with Ursodeoxycholic Acid Tablets

Inform your doctor or pharmacist, if you are taking or have recently taken other medicines. This also applies for medicines obtained without a prescription.

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.

Pregnancy
You should not use this medicine during pregnancy unless your doctor considers it absolutely necessary.

Women of child-bearing potential Even if you are not pregnant, you should discuss this possibility with your doctor, because women of childbearing age may only be treated, if they use a reliable method of contraception. Non-hormonal contraception or contraception with low dose oestrogens is recommended. However, if you use this medicine for solving gallstones, you may only use non-hormonal contraception, because hormonal contraception promotes the formation of gallstones.

Breast-feeding
Tell your doctor if you are breastfeeding or about to start breastfeeding. According to few documented cases of breastfeeding women milk levels of ursodeoxycholic acid in milk are very low and probably no adverse reactions are to be expected in breastfed infants.

Driving and using machines
Ursodeoxycholic Acid has no or negligible influence on driving ability or the ability to operate machines.

3. How to take Ursodeoxycholic Acid Tablets

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

Your doctor will determine your dose based on your body weight.

Take the tablets after a meal with a glass of milk or a small snack. Take the prescribed number of tablets distributed throughout the day.

1. Dissolving of gallstones:
   Four to six tablets of 150mg, two to three tablets of 300mg or two tablets of 450mg per day (600-900mg ursodeoxycholic acid per day).

   Two tablets should always be taken after dinner.

   When taking a dose two or three times daily: for example, one tablet after lunch and two tablets after dinner.

   When taking one dose of two tablets daily: take both tablets preferably two hours after dinner one hour before going to sleep.
2. Primary biliary cholangitis (damage to liver tissue by impaired bile flow):

- Phase I-III:
  four to eight tablets of 150mg, two to four tablets of 300mg, or two tablets of 450mg per day (600-1200mg ursodeoxycholic acid per day).
  Take the prescribed dose in two to three servings per day after meals.
- Phase IV:
  On the basis of liver function examination your doctor will determine if a normal dosage, as in phase I-III, or the half of this dose will be prescribed to you.

Children with cystic fibrosis aged 6 to 18 years

3. Disorders of liver and biliary tract caused by cystic fibrosis (mucoviscidosis):
   four to ten tablets of 150mg, two to five tablets of 300mg, or two to three tablets of 450mg per day (600-1500mg ursodeoxycholic acid per day).

   Take the tablets with a glass of milk or a small snack. Take the prescribed dose in two to three servings per day after meals.

The tablets with a score can be divided if you have problems in swallowing because of the size of the tablets, so that one half tablet can be taken twice directly in sequence.

If you notice that Ursodeoxycholic Acid Tablets is too strong or on the contrary too weak, consult your doctor or pharmacist.

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

If you forget to use Ursodeoxycholic Acid Tablets
Take the prescribed amount at the next regular taking time.
Do not take a double dose to make up for a forgotten dose.

How long should you use Ursodeoxycholic Acid Tablets?
The duration of the treatment depends on the size of the gallstone, but is usually not shorter than three to four months. Treatment should not be interrupted prematurely; even if the symptoms have disappeared. Only an X-ray or an ultrasound scan can show that the gallstones are completely dissolved. After it has been shown with the aid of an echogram that the gallstones have disappeared completely, the treatment should still be continued for three to four months.

The use of Ursodeoxycholic Acid in the treatment of primary biliary cholangitis and disorders of the liver and the biliary system as a result of cystic fibrosis will usually be maintained continuously, in order to continue to maintain the protective effect of Ursodeoxycholic Acid.

Do you have any further questions on the use of this medicine?
Please contact your doctor or pharmacist.

4. Possible side effects

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

Common side effects (occurring in fewer than 1 in 10 patients but more than 1 in 100 patients)
- pasty stools or diarrhoea

Very rare side effects (may affect up to 1 in 10,000 people).
- in the treatment of primary biliary cholangitis: severe pain in the right upper abdomen, severe deterioration (decompensation) of the liver cirrhosis which partially decreases after cessation of treatment;
- calcification of gallstones;
- urticaria (hives).

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 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 Tablets

Keep out of the sight and reach of children.

Do not store above 25°C.

Do not take the tablets 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 tablet becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.

Remember if your doctor tells you to stop using 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 package and other information

What Ursodeoxycholic Acid Tablets contains
The active ingredient is ursodeoxycholic acid.

Each tablet contains 300mg ursodeoxycholic acid.

The other ingredients are Microcrystalline cellulose (Microcel 101) (E460), Polyvinyl pyrrolidone (Plasdone K-90) (E1201), Magnesium Stearate (E572), Sodium Starch Glycolate Type A (Primojel).

What Ursodeoxycholic Acid Tablets looks like and contents of the pack
Ursodeoxycholic Acid Tablets are white to off-white, round shaped uncoated tablets approximately 11.5mm in size with breakline and ´G´ ´443´ engraved on one side and plain on the other side.

It is available in pack size of 60 tablets.

Manufactured by: Glenmark Pharmaceuticals s.r.o., Fibichova 143, 566 17 Vysoké Mýto, Czech Republic.

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

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Call **0208 515 3763** to obtain the leaflet in a format suitable for you.