

APO-URSODEOXYCHOLIC ACID

Contains the active ingredient ursodeoxycholic acid

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about ursodeoxycholic acid. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you or your child.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You or your child may want to read it again.

What this medicine is used for

The name of your medicine is APO-Ursodeoxycholic Acid Capsules. It contains the active ingredient ursodeoxycholic acid.

It is used to treat liver diseases such as:

- primary biliary cirrhosis (PBC)
- primary sclerosing cholangitis (PSC)
- cystic fibrosis (CF)-related cholestasis

Ask your doctor if you have any questions about why this medicine has been prescribed for you or your child. Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

How it works

Ursodeoxycholic acid is a bile acid, which may have a protective effect on the liver by reducing the absorption of other potentially toxic bile salts.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are pregnant.**
Ursodeoxycholic acid may affect your developing baby if you take it during pregnancy.
- **You are breastfeeding.**
Ursodeoxycholic acid may pass into human breast milk.
- **You are hypersensitive to, or have had an allergic reaction to, ursodeoxycholic acid or any of the ingredients listed at the end of this leaflet.**
Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing, difficulty breathing or tightness in chest; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.
If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.
- **The expiry date (EXP) printed on the pack has passed.**
- **The capsules look to be deteriorating in any way**

- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You or your child have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You or your child have or have had any medical conditions, especially the following:
 - a bile duct or gall bladder that is swollen, painful or blocked
 - have kidneys that do not work properly
 - have a gall bladder that cannot be seen on X-ray
 - have calcified gallstones
 - have a gall bladder which is not able to contract properly
 - suffer from frequent cramp-like pains in the upper abdomen (biliary colic)
3. You plan to become pregnant. Do not take this medicine whilst pregnant.
4. You plan to breastfeed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
5. You or your child are planning to have surgery or an anaesthetic.
6. You or your child are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Taking other medicines

Some medicines may interact with ursodeoxycholic acid. These include:

- cholestyramine, colestipol, or statins, medicines used to lower high levels of cholesterol in the blood
- an absorbent such as charcoal

- antacids or medicines used for indigestion that contains aluminium hydroxide and/or smectite (aluminium oxide)
- cyclosporin, medicine used to suppress the immune system
- ciprofloxacin and dapsone, an antibiotic used to prevent certain infections
- nitrendipine (used to treat high blood pressure) and other medicines which are metabolised in a similar way.

If you or your child are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with ursodeoxycholic acid.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

The dose for ursodeoxycholic acid is determined by your body weight. Your doctor should tell you how much ursodeoxycholic acid you or your child should take.

Adults - the usual dose, depending on your weight, is as follows:

For PBC and chronic cholestatic liver diseases other than CF and PSC -

- Two to seven capsules per day.

For CF-related cholestasis -

- Three to nine capsules per day.

For PSC -

- One to nine capsules per day.

Children - the usual dose depends on your child's weight and will be advised by your doctor.

Administration:

Ursodeoxycholic acid should be taken in divided doses, two to three times a day.

For PBC patients - during the first 3 months of treatment, you or your child should take ursodeoxycholic acid capsules in two to three divided doses. With improvement of liver function tests, the daily dose may be taken in one single dose in the evening.

How to take it

Ursodeoxycholic acid capsules should be swallowed whole with a full glass of water because the content is bitter.

Take ursodeoxycholic acid capsules regularly.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

If you or your child needs to take a cholesterol lowering medicine or an antacid, take it at least 2 hours before or 2 hours after the dose of ursodeoxycholic acid.

It does not matter if you take it before, with or after food.

Ursodeoxycholic acid should be taken in divided doses, two to three times a day.

For PBC patients - during the first 3 months of treatment, you or your child should take ursodeoxycholic acid capsules in two to three divided doses. With improvement of liver function tests, the daily dose may be taken in one single dose in the evening.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Ursodeoxycholic acid helps to control you or your child's condition, but does not cure it. It is important to keep taking the medicine even if you or your child feels well.

If you are unsure whether you or your child should stop taking ursodeoxycholic acid, talk to your doctor or pharmacist.

You or your child may need to take ursodeoxycholic acid for many months for it to work.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include diarrhoea. If you or your child suffers from diarrhoea, make sure you or your child drink enough

liquids to replace the fluid and electrolyte balance.

While you are taking this medicine

Things you must do

Tell your doctor that you or your child are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Go to your doctor regularly for a check-up.

Your doctor may do tests to assess you or your child's liver function.

During the first three months of taking ursodeoxycholic acid, your doctor should monitor you or your child's liver function every 4 weeks. After the first three months of taking this medicine, your doctor should monitor you or your child's liver function every 3 months.

See your doctor if you (or your child) feels that you or your child's condition is not improving or is getting worse.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.

- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Possible side effects

Tell your doctor as soon as possible if you or your child do not feel well while you are taking ursodeoxycholic acid or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You or your child may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- Diarrhoea
- Itching/pruritus
- Urticaria (nettle rash)
- Allergic reactions
- Nausea/vomiting
- Sleep disturbance
- Pain in the stomach area or in the upper right part of the belly, under the ribs.

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects and you or your child may need medical attention:

- Severe right-sided upper abdominal pain.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- Severe worsening (decompensation) of liver cirrhosis.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you, or your child, is having an allergic reaction to ursodeoxycholic acid, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing, difficulty breathing or tightness in chest
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Ursodeoxycholic Acid Capsules looks like

250 mg capsule: White hard gelatine capsules. The content - white or almost white powder.

Available in blister pack of 100 capsules

Ingredients

Each capsule contains ursodeoxycholic acid, as the active ingredient.

It also contains the following inactive ingredients:

- maize starch
- silicon dioxide
- magnesium stearate.

Each capsule shell of ursodeoxycholic acid contains:

- Titanium dioxide
- Gelatin

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Ursodeoxycholic Acid 250 mg capsule (Clear PVC/Aluminium silver foil): AUST R 276339.

Sponsor

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This leaflet was last updated in: March 2017.