PATIENT INFORMATION LEAFLET FOR

URSOFALK

SCHEDULING STATUS: S3

URSOFALK, 250 mg ursodeoxycholic acid, capsules

Ursodeoxycholic acid

Sugar free

Read all of this leaflet carefully before you start taking URSOFALK

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- URSOFALK has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What URSOFALK is and what it is used for

Ursodeoxycholic acid, the active substance in URSOFALK capsules belongs to a class of medicine known as bile acids and derivatives, acting on the gastro-intestinal tracts as naturally occurring bile acid.

URSOFALK is indicated for the treatment of:

- For the treatment of a disease called primary biliary cholangitis (PBC), provided there is no complications of the liver, called cirrhosis or
- To dissolve gallstones caused by excess cholesterol in the gall bladder where the gallstones are not visible on a plain X-Ray (gallstones that are visible will not dissolve) and not more than 15 mm in diameter. The gall bladder should still be working despite the gallstone(s).

2. What you need to know before you take URSOFALK

Do not take URSOFALK if:

- You are hypersensitive (allergic) to ursodeoxycholic acid or any of the other ingredients of URSOFALK (listed in **section 6**).
- You suffer from inflammation or blockage of the gall bladder or biliary tract.
- You have a blockage of the common bile duct or cystic duct (obstruction of the biliary tract).
- You are pregnant or planning to become pregnant (see **Pregnancy, breastfeeding and fertility**).
- You suffer from frequent cramp-like pains in the upper abdomen (biliary colic).
- Your gall bladder is not able to contract or function properly.

- You were diagnosed with radio-opaque or calcified gallstones (gallstone that are visible on an X-Ray).

Warnings and precautions

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-month intervals.

When used in the treatment of primary biliary cholangitis PBC, in rare cases the symptoms (such as itching) may worsen at the beginning of treatment. If this happens, please speak to your doctor about reducing your initial dose.

Please inform your doctor immediately if you have diarrhoea, as this may require a reduction in the dose or discontinuation of treatment.

When used to dissolve gallstones, your doctor should arrange for a scan of your gall bladder after the first 6 to 10 months of treatment.

Female patients taking URSOFALK to dissolve of gallstones should use an effective non-hormonal method of contraception such as male or female condoms, since hormonal contraceptives may increase gallstone formation (biliary lithiasis) see **Pregnancy, breastfeeding and fertility**.

Other medicines and URSOFALK

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Inform your doctor if you take the following medicines:

- Cholestyramine, colestipol (to lower blood cholesterol) or antacids containing aluminium hydroxide and or aluminium oxide (smectite) since URSOFALK reduces the effect of

these medicines. If you must take medication that contains any of these ingredients, it must be taken at least two hours before or after URSOFALK.

- Ciclosporin. In patients receiving ciclosporin treatment, blood concentrations of this substance should be checked by the doctor and the ciclosporin dose adjusted if necessary because URSOFALK can affect the absorption of ciclosporin.
- Ciprofloxacin and dapsone (antibiotics), nitrendipine (used to treat high blood pressure). It may be necessary for your doctor to alter the dose of these medicines because URSOFALK reduces the effect of these medicines.
- Rosuvastatin (for high cholesterol and related conditions) as URSOFALK may alter the effect of this medicine.

If you are taking URSOFALK capsules 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 URSOFALK.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking URSOFALK. Do not take URSOFALK if you are pregnant or breastfeeding. Safety in pregnancy and breastfeeding has not been established.

Women of childbearing age should be treated only if they use reliable contraception: non-hormonal or low-oestrogen oral contraceptive measures are recommended. However, patients taking URSOFALK capsules to dissolve gallstones must use an effective non-hormonal contraceptive such as male or female condoms, since hormonal oral contraceptives may increase

gallstone formation (biliary lithiasis). Pregnancy must be excluded before the beginning of treatment.

Driving and using machines

URSOFALK has no or negligible influence on the ability to drive and use machines.
It is not always possible to predict to what extent URSOFALK may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which URSOFALK affects them.

3. How to take URSOFALK

Do not share medicines prescribed for you with any other person.
Always take URSOFALK exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.

URSOFALK is for you. Please do not give it to anyone else, even if they have the same symptoms as you.

Your doctor will determine the correct dose for you based on your condition and body mass. Do not stop your treatment early because you have the impression that the effect of URSOFALK is too strong or too weak, tell your doctor or pharmacist.

For the treatment of primary biliary cholangitis (PBC) chronic inflammation of the bile ducts:
The daily dosage depends on bodyweight and is approximately 3 to 7 capsules taken orally (12 to 16 mg per kg of body weight). The following regimen is recommended:

During the first 3 months of treatment, you should take URSOFALK capsules in the morning, at midday and in the evening. As your liver function values improve, the total daily dose may be taken once a day in the evening.

Body weight (BW) in kg	**Daily dose (mg/kg BW)**	**URSOFALK 250 mg hard capsules**			
		First 3 months			**Subsequently**
		Morning	**Midday**	**Evening**	**Evening (1 x daily)**
47 to 62	12 to 16	1	1	1	3
63 to 78	13 to 16	1	1	2	4
79 to 93	13 to 16	1	2	2	5
94 to 109	14 to 16	2	2	2	6
Over 110		2	2	3	7

To dissolve of gallstones:

Adults: The usual dose is 8 to 12 mg/kg/day to be taken orally in the evening, e.g. 750 mg, daily in the evening. It generally takes 6 to 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. At each of these follow-up examinations, it should be checked whether a build-up of calcium causing hardening of the stones has occurred since the last time. If this happens, your doctor will stop the treatment.

The capsules should be swallowed whole with some liquid. Care should be taken to ensure that they are taken regularly.

If you take more URSOFALK than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Show the pack to the doctor**.**

Diarrhoea may occur as a result of overdose. 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.

If you forget to take a dose of URSOFALK

If you forget to take a dose, leave out that dose completely. Take your next dose at the normal time it is due. Do not take a double dose to make up for the dose that you missed.

Always speak to your doctor before you decide to interrupt treatment with URSOFALK capsules or decide to stop your treatment early.

4. Possible side effects

URSOFALK can have side effects.

Not all side effects reported for URSOFALK are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking URSOFALK, please consult your health care provider for advice.

If any of the following happens, stop taking URSOFALK and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to

URSOFALK. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- Frequent side effects:
    - Reports of pasty stools or diarrhoea.

- Less frequent side effects:
    - Severe right-side upper stomach pain during treatment of PBC.
    - Calcification (formation) of gallstones.
    - Itching and hives, nettle rash (urticaria).
    - Severe worsening (decompensation) of liver disease (cirrhosis), during treatment of the advanced stages of PBC, which partially improve when treatment is stopped.

- Side effects with unknown frequency:
    - Nausea, vomiting, dyspepsia and constipation.
    - Pruritus (severe itching)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of URSOFALK.

5. How to store URSOFALK

Store at or below 25 °C. Protect from light.

If you don't need to use this medicine anymore, take it to your doctor or nearest pharmacy who will dispose of it.

Do not use after the expiry date stated on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Store all medicines out of reach of children.

6. Contents of the pack and other information

What URSOFALK contains

The active substance is 250 mg ursodeoxycholic acid.

The other ingredients are colloidal anhydrous silica, gelatine, magnesium stearate, maize starch, purified water, sodium lauryl sulphate and titanium dioxide.

What URSOFALK looks like, and contents of the pack

URSOFALK is a white, opaque, hard gelatine capsules, size 0, containing a white, compressed powder or granules.

URSOFALK is packed in transparent PVC/Aluminium blisters. 50, 100 or 200 capsules are packed in a cardboard carton.

Holder of certificate of registration

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Access to the corresponding Professional Information

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PLACE HOLDER: The QR Code to be generated and included after approval.