SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Finished Pharmaceutical Product

1.1 Proprietary Name

URSOLIV 250

1.2 Strength

Ursodeoxycholic Acid 250 mg

1.3 Pharmaceutical Form

Hard gelatin capsules

2. Qualitative and Quantitative composition

2.1 Qualitative Declaration

Recommended International Non-proprietary name (INN): Ursodeoxycholic acid

2.2 Quantitative Declaration

Each capsule contains:

Ursodeoxycholic acid ..... 250.00 mg

3. Pharmaceutical Form

Hard gelatin capsules.

White to off-white powder filled in size “0” oblong, opaque, white color, hard gelatin shell capsule.

4. Clinical Particulars

4.1 Therapeutic Indications

- Dissolution of gallstones in patients with radiolucent, noncalcified, gallbladder stones less than 20 mm diameter in whom elective cholecystectomy would be undertaken except for the presence of increased surgical risk due to systemic disease, advanced age, idiosyncratic reaction to general anesthesia, or for patients who refuse surgery.
- Prevention of gallstone formation in obese patients experiencing rapid weight loss.
- Compensated primary biliary cirrhosis.
- Chronic cholestatic syndrome various liver lesions.

SUMMARY OF PRODUCT CHARACTERISTICS

4.2 Posology and method of administration

- Gallstones Dissolution:

The recommended oral dose for treatment of gallstone disease is 8-10 mg/kg/day given in 2 or 3 divided doses with meals.

Duration of therapy 6-12 months. After complete dissolution, it is recommended that Ursoliv be continued for at least 3 months to promote dissolution of particles that are too small to image.

- Gallstone Prevention:

To prevent gall stone formation in obese patient experiencing rapid weight loss the recommended dose is 800 mg twice a day with meals.

- Cholestatic liver diseases:

The recommended oral dose for treatment of cholestatic liver diseases is 13-15 mg/kg/day given in 2 divided doses with meals.

- Primary biliary cirrhosis:

The daily dose of 10-15 mg/kg/day in divided dose.

Body weight	Daily dose	Morning	Afternoon	Evening
Up to 60 kg	2 caps	1	-	1
60-80 kg	3 caps	1	1	1
80-100 kg	4 caps	1	1	2

Special population

Use during pregnancy and lactation:

Should not be used during pregnancy and lactation without medical advice.

Use in pediatrics:

Safety and efficacy have not been established.

Method of Administration: Oral

4.3 Contraindications

Ursoliv must not be used in the presence of:

- Allergy to bile acids.
- Patients with gallstone complications such as biliary-gastrointestinal fistula, biliary obstruction, cholangitis, cholecystitis, pancreatitis or frequent biliary colic.

Ursoliv is ineffective for the dissolution of calcified and pigment gallstones and is of no value in patients without a patent and functioning gall bladder.

SUMMARY OF PRODUCT CHARACTERISTICS

4.4 Special Warnings and Precautions for Use

Use during pregnancy and lactation:

Should not be used during pregnancy and lactation without medical advice.

Use in pediatrics:

Safety and efficacy have not been established.

Liver tests:

Patients given ursodeoxycholic acid should have SGPT (ALT), SGOT(AST), GGT, ALP and bilirubin measured at the initiation of therapy and thereafter as indicated by the particular clinical circumstances. Monitoring of serum values is recommended upon initiation of treatment, every 1 to 3 months for the first 3 months of treatment (depending on the indication for use), and then every 6 months during treatment; ursodeoxycholic acid must be discontinued if increased values persist.

4.5 Interaction with other medicinal products and other forms of Interaction

Should not be taken at the same time as antacids containing aluminium, cholestyramine, colestipol, antihyperlipidemics, especially clofibrate, estrogens, neomycin, oral contraceptives or progestins as these preparations bind ursodeoxycholic acid in the intestine, thus impairing absorption and efficacy.

4.6 Pregnancy and Lactation

Should not be used during pregnancy and lactation without medical advice.

Fertility

None.

4.7 Effects on Ability to Drive and Use Machines

Effects on ability to drive and use machinery have not been observed.

4.8 Undesirable Effects

Based on the provided Patient Information Leaflet, here is the requested information about ursodeoxycholic acid.

a. Summary of the Safety Profile

Ursodeoxycholic acid is a medication used for the dissolution of gallstones, prevention of gallstone formation in obese patients with rapid weight loss, and treatment of cholestatic liver diseases, including primary biliary cirrhosis. The medication should not be used in patients with an allergy to bile acids, or those with gallstone complications such as biliary-gastrointestinal fistula, biliary obstruction, cholangitis, cholecystitis, pancreatitis, or frequent biliary colic. Ursodeoxycholic acid is also ineffective for calcified and pigment gallstones and should not be used in patients without a patent and functioning gallbladder. Adverse reactions may include allergy, cholecystitis, leucopenia, peptic ulcer, and urinary tract infection.

b. Tabulated Summary of Adverse Reactions

The provided document lists the following adverse reactions:

System Organ Class	Adverse Reactions
Immune System	Allergy 5
Hepatobiliary	Cholecystitis 6
Hemic and Lymphatic	Leucopenia 7
Gastrointestinal	Peptic ulcer 8
Genitourinary	Urinary tract infection 9

c. Description of Selected Adverse Reactions

May cause allergy, cholecystitis, leucopenia, peptic ulcer and urinary tract infection.

d. Paediatric Population

The safety and efficacy of ursodeoxycholic acid have not been established in the pediatric population

e. Other Special Population(s)

Pregnancy and Lactation: Ursodeoxycholic acid should not be used during pregnancy and lactation without medical advice

Liver Function: Patients should have liver function tests (SGPT/ALT, SGOT/AST, GGT, ALP, and bilirubin) measured at the start of therapy, and then monitored every 1 to 3 months for the first 3 months, and every 6 months thereafter. The medication must be discontinued if increased values persist.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

4.9 Overdose

No cases of Ursodeoxycholic acid overdose have been reported.

The most likely manifestation of severe overdose with Ursodeoxycholic acid would probably be diarrhea, which should be treated symptomatically.

Paediatric population

The safety and efficacy of ursodeoxycholic acid have not been established in the pediatric population

SUMMARY OF PRODUCT CHARACTERISTICS

5. Pharmacological properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group and ATC code: Bile acid preparations; A05AA02

The mechanism of Ursodeoxycholic acid is anticholelithic action is not completely understood, it is known that when administered orally Ursodeoxycholic acid is concentrated in bile and decreases biliary cholesterol saturation by inhibiting its intestinal absorption. The reduced cholesterol saturation permits the gradual solubilization of cholesterol from gallstones, resulting in their eventual dissolution.

Ursodeoxycholic acid increases bile flow. In chronic cholestatic liver disease, Ursodeoxycholic acid appears to reduce the detergent properties of the bile salts, thus reducing their cytotoxicity. Also, Ursodeoxycholic acid may protect liver cells from the damaging activity of toxic bile acids (e.g., lithocholate, deoxycholate, and chenodeoxycholate), which increase in concentration in patients with chronic liver disease.

Paediatric population

The safety and efficacy of ursodeoxycholic acid have not been established in the pediatric population

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5.2 Pharmacokinetic Properties

· Absorption: Ursodeoxycholic acid is absorbed from the small bowel, with approximately 90% of the dose being absorbed. The time to peak concentration is 1 to 3 hours.

· Distribution: Ursodeoxycholic acid is extensively bound to plasma proteins.

· Biotransformation: Ursodeoxycholic acid undergoes hepatic (first-pass hepatic clearance) metabolism in the liver to its taurine and glycine conjugates. The resulting conjugates are secreted into bile.

· Elimination: The half-life of administered Ursodeoxycholic acid is 3.5 to 5.8 days. Excretion is primarily fecal, with very small amounts being excreted into the urine. A small amount of unabsorbed Ursodeoxycholic acid passes into the colon where it is degraded by bacteria, and the resulting lithocholic acid is partially absorbed, sulfated in the liver, and rapidly eliminated in the feces.

· Linearity/non-linearity: Not Applicable

Paediatric population

The safety and efficacy of ursodeoxycholic acid have not been established in the pediatric population

5.3 Preclinical Safety Data

Not applicable.

SUMMARY OF PRODUCT CHARACTERISTICS

6. Pharmaceutical Particulars

6.1 List of Excipients

Corn Starch, Starch 1500, Aerosil 200, Magnesium Stearate Pharmagrade, Empty hard gelatin capsule shell.

6.2 Incompatibilities

None.

6.3 Shelf Life

24 months

6.4 Special Precautions for Storage

Store below 30°C in a dry place, away from direct sunlight.

6.5 Nature and Contents of Container

Ursoliv 250 is available as 10 hard gelatin capsules packed in a Alu-PVC/PVDC blister, 5 such blisters further packed in a cardboard carton alongwith a pack insert.

6.6 Special precaution for disposal and other handling

No special requirements.

7. Marketing Authorization Holder and Manufacturing Site

Addresses Marketing Authorization Holder:

MEGA LIFESCIENCES Public Company Limited

384 Moo 4, Soi 6, Bangpoo Industrial Estate, Pattana 3 Road, Phraeksa,

Mueang, Samutprakarn 10280, Thailand.

Manufacturing Site Address:

MEGA LIFESCIENCES Public Company Limited

515/1 Moo 4, Soi 8, Bangpoo Industrial Estate, Pattana 3 Road,

Phraeksa, Mueang, Samutprakarn 10280, Thailand.

8. Marketing Authorization Number: H2020/CTD7525/14617

9. Date of first Registration: May 29, 2020

10. Date of revision of the text: July 2025

11. Dosimetry: Not Applicable

12. Instruction for preparation of Radiopharmaceuticals(If Applicable): Not Applicable