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The Japanese Pharmacopoeia Ursodeoxycholic Acid tablets

Class-3 pharmaceutical product

TANABE ICHOYAKU URSO

Medicine for the digestive organ

**Urso continues to be used to maintain the digestive tract,
improving the pleasure of eating.**

Because of enterohepatic circulation:

Ursodeoxycholic acid (UDCA) is absorbed in the intestines, and passes through the liver and gall bladder, to be released into the intestines, where it is reabsorbed. This cycle is termed "enterohepatic circulation", and it means that UDCA is effective for a prolonged period, in the liver and gall bladder as well as the stomach and intestines. As a result, administration of one tablet per day is effective for maintenance of the digestive tract.

Due to promotion of biliary acid secretion:

Heavy stomach can be a result of aging, or due to eating greasy food. One cause is reduced secretion of the biliary acids that aid absorption of fats and oils. UDCA promotes secretion of biliary acids, and thus alleviates heavy stomach and indigestion due to accumulation of fats.

PRECAUTIONS



CONSULTATION

- 1. Consult a doctor, pharmacist or registered retail person before use if**
 - (1) you are under the care of a doctor
 - (2) you are pregnant or suspected of being pregnant
 - (3) you have ever had an allergic reaction to a medical product, etc.
- 2. Discontinue use immediately and consult a doctor, pharmacist or registered retail person showing this package insert if any of the following symptoms occur after the medication, since it can be an adverse reaction.**

Affected area	Symptoms
Skin	Rash/redness, itching
Digestive organ	Diarrhea, nausea

- 3. If such symptoms have not resolved after an approximately 2-week medication period, discontinue use and consult a doctor, pharmacist, or registered retail person showing this package insert.**

INDICATIONS

Upset stomach, Indigestion, Feeling of fullness in the stomach or abdomen due to indigestion, Loss of appetite, Promotion of digestion, Overeating, Chest discomfort

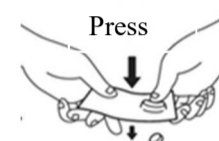
DOSAGE AND ADMINISTRATION

Take one tablet per day, before or after the evening meal.

Age	Dosage	Frequency (per day)
Adults and children ≥ 15 years of age	1 tablet	1 time
Children < 15 years of age	Not recommended	

< Precautions for dosage and administration >

- (1) Strictly follow the DOSAGE AND ADMINISTRATION.
- (2) **How to remove the tablets from blisters:**
Take out one tablet by pressing the blister of the PTP sheet that contains the tablet and breaking the aluminum foil on the back, as shown in the right illustration.
(Misadministration of the sheet may lead to an unexpected accident for example a puncture on mucosa.).



COMPOSITION (in one tablet, i.e. one daily dose)

Ursodeoxycholic acid 50 mg

Additives: hydroxypropylcellulose, stearic acid Mg, cellulose, corn starch, carmellose Ca, light anhydrous silicic acid

PRECAUTIONS FOR STORAGE AND HANDLING

- (1) Store in a cool, dry place, away from direct sunlight.
- (2) Keep out of reach of children.
- (3) Do not transfer or store in another container.
(May lead to misuse or quality deterioration.)
- (4) Do not use this drug after the expiration date.



Manufactured and distributed by
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