METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

2233-TDS-ENG-2019

ACIDO URSODESOXICOLICO (PH.EUR)		
DESCRIPTION DCI: URSODESOXYCHOLIC ACID	DESCRIPTION DOE: URSODESOXICOLICO ACIDO	
CAS Nº: 128-13-2	EC Nº: 204-879-3	AEMPS CODE: 1174A
MOL. WEIGHT: 392.6	MOL. FORMULA: C24H40O4	ARTICLE CODE: 2233

ATTRIBUTES	SHOULD BE
Appearance	White or almost white powder
Solubility	Practically insoluble in water, freely soluble in ethanol (96 %), slightly soluble in acetone, practically insoluble in methylene chloride
Identification A	Complies
Melting point	about 202 ºC
Specific optical rotation	+58.0º / +62.0º
Impurity C	=< 0.1 %
Related substances	
Impurity A	=< 1.0 %
Any other impurity	=< 0.10 %
Total impurities	=< 1.5 %
Loss on drying	=< 1.0 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 9.0

STORAGE

Keep the container tightly closed in a cool and dry place. Keep away from sources of heat and ignition.

REMARKS

URSODEOXYCHOLIC ACID is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE are available upon request.

Properties and uses
URSODEOXYCHOLIC ACID is a natural bile acid present in small amounts in human bile. URSODEOXYCHOLIC ACID suppresses the synthesis and secretion of cholesterol by the liver and inhibits the intestinal absorption of cholesterol. URSODEOXYCHOLIC ACID is absorbed in the digestive tract and undergoes an enterohepatic cycle. It is partially conjugated in the liver before being excreted by bile. Due to influences of intestinal bacteria, the free and conjugated forms undergo 7α-dehydroxylation to lithocholic acid, part of which is directly excreted in the faeces and the rest absorbed, and mainly conjugated and sulfated by the liver, before its excretion. by the stool. However, in comparison with chenodeoxycholic acid, URSODEOXYCHOLIC ACID suffers less bacterial degradation. It is used for the dissolution of high cholesterol gallstones in patients with functional gall bladder, and in primary biliary cirrhosis. The time required for the dissolution of the gallstones is presumably between 6 and 24 months depending on the size and composition of the stone.
URSODEOXYCHOLIC ACID is the drug of choice since it is more effective and is associated with fewer adverse effects than chenodeoxycholic acid. URSODEOXYCHOLIC ACID has been tried in the treatment of primary sclerosing cholangitis.

Dosage
Gallstones: usually 6 - 12 mg / kg / day.
Primary biliary cirrhosis: usually 10 to 15 mg / kg / day.

Side effects
URSODEOXYCHOLIC ACID can cause nausea, vomiting and other digestive disorders, but diarrhea has been reported to occur less frequently than with deoxycholic acid. Increases in liver enzyme values are also less likely. Itching may appear.

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The treatment with URSODEOXYCHOLIC ACID can cause more calcifications of cholesterol calculation than chenodeoxycholic acid. URSODEOXYCHOLIC ACID should not be administered to patients with chronic liver disease, peptic ulcers or inflammatory bowel disease. It is not effective in dissolving pigmented and calcified gallstones, and is not useful in patients who do not have a manifest and functional gallbladder. It should be avoided during pregnancy.

Interactions
URSODEOXYCHOLIC ACID should not be used with drugs such as estrogen hormones, which increase biliary cholesterol. Concomitant administration with drugs that bind to bile acid, such as antacids, charcoal and cholestyramine, should be avoided, since it may reduce the efficacy of URSODEOXYCHOLIC ACID treatment.

Formulation examples

Choleretic capsules

URSODEOXYCHOLIC ACID - **150-300 mg**
Excipient c.s.p - **1 capsule**