

ALLERGEN DECLARATION

Product name: URSODIOL, USP/EP
Stock code: 1987
Starting material: Cholic Acid (Bovine bile)
Manufactured via: Chemical Synthesis

BSE/TSE: URSODIOL is manufactured using Cholic Acid purchased from qualified suppliers, in possession of currently valid Certificates of Suitability issued by the European directorate for the Quality of Medicines. Cholic Acid which is produced from bovine bile deriving from animals bred in countries free of risk of contamination from BSE/TSE without the use of fodder containing meat meal. Therefore the product is free of contamination due to BSE/TSE in compliance with European note one “guidance EMEA/410/01 rev3 regarding minimizing the risk of transmitting Animal Spongiform Encephalopathy”.

GMO: Product does not contain any GMO material.

Allergen: Please note that there may be several steps before the raw material is produced and access to data on manufacturing raw materials is not easily obtained for the starting materials and intermediates used in the production process. The following items are not used in the manufacturing process of the product, and although manufacturer does not specifically assay for the presence of the items below, it is unlikely that any traces of these items are present in the starting materials or in the final product.

The product is unlikely to contain the following -
<input checked="" type="checkbox"/> Cereals containing gluten and products thereof
<input checked="" type="checkbox"/> Corn and products thereof
<input checked="" type="checkbox"/> Celery and products thereof
<input checked="" type="checkbox"/> Soybeans and products thereof
<input checked="" type="checkbox"/> Yeast
<input checked="" type="checkbox"/> Fish and crustacean shellfish and products thereof
<input checked="" type="checkbox"/> Eggs and products thereof
<input checked="" type="checkbox"/> Dairy Products (Milk, Lactose, Caseinates, Whey)
<input checked="" type="checkbox"/> Peanuts and products thereof
<input checked="" type="checkbox"/> Tree nuts (oils) or derivatives
<input checked="" type="checkbox"/> Mustard and products thereof
<input checked="" type="checkbox"/> Sesame Oil
<input checked="" type="checkbox"/> Preservatives
<input checked="" type="checkbox"/> Sulfites >10ppm
<input checked="" type="checkbox"/> Artificial Colours and Flavours
<input checked="" type="checkbox"/> Chicken/Pork derivatives

This allergen statement is provided for **informational purposes** only, based on product knowledge and manufacturing process, as instructed to MEDISCA by the manufacturer, and is not meant to be a guarantee of absence of the above stated allergens.

This statement substitutes all previous versions issued for the above-mentioned product(s).

We trust this information, which is made up to the best of our knowledge, will be helpful to you.

With kind regards,
The MEDISCA Team