

ALLERGEN DECLARATION

Product name: ESTRADIOL, USP (HEMIHYDRATE) (MICRONIZED)

Stock code: 0869

Starting material: Phytosterol (extracted from soy, corn, etc.)

Manufactured via: what is best described as a semi-synthetic process using a mixture of vegetable sterols that are isolated from various starting materials, such as soy, yam, corn, etc. This is a chemicals isolation, that yields the *pure* chemical itself. This pure chemical is then converted through several fermentation and chemical processing steps to yield the API. Therefore, this steroid is synthetic and have very little to do with the plant that was used in the preliminary stages.

BSE/TSE: Based on the ingredients, the product is in compliance with the note for the guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products.

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 type="checkbox"/> Corn and products thereof
<input checked="" type="checkbox"/> Celery and products thereof
<input type="checkbox"/> Soybeans and products thereof (note that the sterols used to manufacture the starting materials for the steroid hormone are not proteins and therefore are not classified as soy allergens.)
<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 Colors and Flavors
<input checked="" type="checkbox"/> Beef/Chicken/Pork derivatives

This allergen statement is for the use of the product in pharmaceutical compounding and is provided for informational purposes only. It is based on information received from the manufacturer concerning the product contents and manufacturing process, and Medisca makes no representations, and takes no responsibility for the content thereof. No analytical testing has been performed by Medisca or by the manufacturer for these allergens, and representations concerning their presence in trace amounts are based on theoretical considerations. Accordingly, this statement should not be taken as a guarantee of the absence of the above-stated allergens.

This statement replaces all previous versions for the above-mentioned product.

We trust this information, which is made to the best of our knowledge in conformance with the foregoing, will be helpful to you.

With kind regards,

The MEDISCA Team