

ALLERGEN DECLARATION

Product name: PROGESTERONE, USP

Stock code: 3169

Starting material: Vegetable sterol from yam

Manufactured via: The process is best described as semi-synthetic, starting with vegetable sterols that are chemically isolated from various plant sources. This isolation step yields a pure sterol compound, which then undergoes several fermentation and chemical processing steps to produce the steroid hormone. As a result, while the starting material is plant derived, the final steroid is synthetic and has minimal relation to the original plant source beyond the initial isolation stage.

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 checked="" type="checkbox"/> Corn and products thereof
<input checked="" type="checkbox"/> Celery and products thereof
<input checked="" 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