

ALLERGEN DECLARATION

PRODUCT NAME: PROGESTERONE, USP (Micronized) - 0043

1. The starting material (source) is:

- | | | |
|--------------------------------------|--|---|
| <input type="checkbox"/> All-natural | <input type="checkbox"/> Animal-based: | _____ |
| <input type="checkbox"/> Synthetic | <input checked="" type="checkbox"/> Vegetable-based: | <u>Soy or Yam (refer to Medisca CofA)</u> |

BSE/TSE: No raw material sourced or derived from animals are used in the manufacturing. Hence, the materials used in the production of have demonstrated compliance with the note for the guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products.

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 end product –

2. The product is unlikely to contain the following -
<input checked="" type="checkbox"/> Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof
<input checked="" type="checkbox"/> Crustaceans and products thereof
<input checked="" type="checkbox"/> Corn
<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 products thereof
<input checked="" type="checkbox"/> Eggs and products thereof
<input checked="" type="checkbox"/> Dairy Products (Milk, Lactose, Caseinates, Whey)
<input checked="" type="checkbox"/> Sugar
<input checked="" type="checkbox"/> Sodium/Salt
<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"/> Sunflower Oil
<input checked="" type="checkbox"/> Sulfites/Bisulfites
<input checked="" type="checkbox"/> Artificial Colours and Flavours
<input checked="" type="checkbox"/> Genetically-modified organisms (GMOs)
<input checked="" type="checkbox"/> Beef/Chicken/Pork derivatives

3. The product is made via by 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 or yam. These vegetable sterols are processed through several fermentation and chemical processing steps to yield the API.

Please be advised that Medisca has not tested for the presence of the above stated allergens. Therefore, this statement is provided for **informational purposes** only, as instructed to Medisca by the manufacturer, and is not meant to be a guarantee of absence of the above stated allergens.

Prepared by: Henrietta Wetzler
Title: Document Control Team Leader

Signature: 