



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	163208	Bulgarian Tribulus Complex
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Herbs of Gold Pty Ltd	
<b>Postal Address</b>	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
<b>ARTG Start Date</b>	8/07/2009	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Listed Medicines	

### Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

### Products

#### 1 . Bulgarian Tribulus Complex

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	19/05/2021
---------------------	-------------------------	-----------------------	------------

### Permitted Indications

Traditionally used in Ayurvedic medicine to vrishya/aphrodisiac/Increase in virility

Maintain/support healthy female hormonal balance during menopause

Traditionally used in Ayurvedic medicine to aphrodisiac/Enhance/improve/promote healthy libido

Maintain/support healthy libido in males

Maintain/support healthy libido in females

Maintain/support healthy libido in post-menopausal women

Maintain/support healthy sexual function in post-menopausal women

Maintain/support healthy sexual function in females

Maintain/support healthy sexual function in males

Traditionally used in Ayurvedic medicine to male tonic

Maintain/support sperm health

Maintain/support sperm motility

Maintain/support sperm production

### Indication Requirements

Product presentation must not imply or refer to infertility.

If Ayurvedic terminology is used on medicine label, label statement: Talk to a Ayurvedic practitioner/health professional if you are unsure if this medicine is right for you.

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

### Warnings

No Warnings included on Record

### Additional Product information

Public Summary



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>Tribulus terrestris fruit Extract dry concentrate standardised</b>	<b>666.667 mg</b>
Equivalent: Tribulus terrestris (Dry)	10000.005 mg
<b>Tribulus terrestris herb Extract dry concentrate standardised</b>	<b>90.911 mg</b>
Equivalent: furostanol saponins calc as protodioscin (of Tribulus terrestris) ()	40.9099 mg

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
colloidal anhydrous silica  
crospovidone  
hypromellose  
macrogol 400  
magnesium stearate  
microcrystalline cellulose  
sodium starch glycollate

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary