



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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

Product Type	Single Medicine Product	Effective Date	19/05/2021
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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 females
Maintain/support healthy libido in males
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



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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	
Tribulus terrestris fruit Extract dry concentrate standardised	666.667 mg
Equivalent: Tribulus terrestris (Dry)	10000.005 mg
Tribulus terrestris herb Extract dry concentrate standardised	90.911 mg
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	

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