



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	214848	V-DRIVE MEN
ARTG entry for	Medicine Listed	
Sponsor	Phytologic Holdings Pty Ltd	
Postal Address	PO Box 6193, Alexandria, NSW, 2015 Australia	
ARTG Start Date	20/09/2013	
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 . V-DRIVE MEN

Product Type	Single Medicine Product	Effective Date	4/12/2020
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Permitted Indications

Maintain/support energy levels
Maintain/support vitality
Maintain/support general health and wellbeing
Maintain/support healthy body fat/muscle composition
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support healthy muscle contraction function
Maintain/support muscle health
Helps enhance/promote healthy muscle function
Helps enhance/improve/promote/increase muscle performance/endurance/stamina
Maintain/support muscle performance/endurance/stamina
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Decrease/reduce mental/cognitive fatigue
Maintain/support cognitive function/mental function
Maintain/support reproductive system health
Aphrodisiac/Enhance/improve/promote healthy libido
Maintain/support healthy libido in males
Maintain/support healthy sexual function in males
Maintain/support sperm health in males
Maintain/support sperm production in males
Maintain/support testosterone level in males

Indication Requirements

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

Product presentation must not imply or refer to chronic fatigue syndrome.

Product presentation must not imply or refer to serious immunological diseases.



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Product presentation must not imply or refer to infertility.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

magnesium aspartate	200.9 mg
Equivalent: magnesium	16.875 mg
pyridoxine hydrochloride	6 mg
Equivalent: pyridoxine	4.9 mg
Trigonella foenum-graecum seed Extract dry concentrate	300 mg
Equivalent: Trigonella foenum-graecum (Dry)	9.9 g
zinc amino acid chelate	75 mg
Equivalent: zinc	15 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
citric acid
croscarmellose sodium
Gelatin
magnesium stearate
microcrystalline cellulose
Oryza sativa
silicon dioxide

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