



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	307062	GenoMulti Active B
ARTG entry for	Medicine Listed	
Sponsor	Bio-Practica Pty Ltd	
Postal Address	651 Portrush Road, GLEN OSMOND, SA, 5064 Australia	
ARTG Start Date	16/07/2018	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . GenoMulti Active B

Product Type	Single Medicine Product	Effective Date	12/03/2019
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support collagen formation
- Maintain/support energy levels
- Helps convert (state food) into energy
- Maintain/support energy production
- Maintain/support healthy eye function
- Maintain/support eye health
- Maintain/support healthy eyesight/vision
- Maintain/support body mucous membrane health
- Maintain/support general health and wellbeing
- Maintain/support hair growth
- Maintain/support hair health
- Maintain/support healthy teeth
- Aid/assist nail growth
- Maintain/support nail health/strength/thickness
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support healthy body tissues

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Maintain/support bone health
Maintain/support bone strength
Help maintain/support bone mineralisation
Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life
Aid/assist healthy red blood cell production
Maintain/support red blood cell health
Helps maintain/support healthy cholesterol in healthy individuals
Helps maintain/support healthy blood sugar/glucose in healthy individuals
Maintain/support blood health
Helps maintain/support transport of oxygen in the body
Aid/assist/helps oxygen transport to body tissues
Helps maintain/support haemoglobin formation/synthesis
Maintain/support healthy cardiovascular system function
Maintain/support heart health
Maintain/support blood capillary health
Maintain/support blood vessel health
Maintain/support healthy thyroid gland function
Maintain/support healthy thyroid gland function in healthy adults
Maintain/support healthy thyroid hormones
Maintain/support healthy thyroid hormones in healthy adults
Maintain/support thyroid gland health
Aid/assist thyroid hormone production in healthy adults
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support muscle function
Maintain/support healthy neuromuscular system/function
Aid/assist/helps glucose/sugar/carbohydrate metabolism
Aid/assist/helps protein synthesis in the body
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in elderly individuals
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when sun exposure is inadequate
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Aids/assists the body to cope with environmental stress
Support healthy stress response in the body
Maintain/support cognitive function/mental function in healthy adults
Maintain/support cognitive function/mental function
Maintain/support nerve conduction
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support female reproductive system health
Maintains/support healthy foetal development
Maintain/support healthy pregnancy
Maintain/support maternal health
Maintain/support preconception health in healthy females
Maintain/support preconception health in healthy males
Maintain/support reproductive system health in males
Maintain/support healthy reproductive hormones
Maintain/support sperm health in healthy males
Maintain/support sperm motility in healthy males
Maintain/support sperm production in healthy males
Maintain/support testosterone level
Maintain/support skin health

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Maintain/support skin integrity/structure
 Maintain/support skin regeneration
 Maintain/support wound healing

Indication Requirements

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Product presentation must not imply or refer to serious cardiovascular conditions.

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).

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

Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

Label statement: If symptoms persist, talk to your health professional.

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

Product presentation must not imply or refer to heart disease.

Product presentation must not imply or refer to any thyroid related diseases.

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

Product presentation must not imply or refer to infertility.

Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose of 25 micrograms or less of vitamin D and as a minimum, also contain at least 25% of the RDI in the recommended daily dose of vitamin D.

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

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 hormone imbalances.

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 lowering or raising blood cholesterol levels from outside of the normal healthy range

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

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

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

betacarotene	3 mg
Biotin	150 microgram
calcium ascorbate dihydrate	121 mg

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Equivalent: ascorbic acid	100 mg
calcium folinate	108.038 microgram
Equivalent: folic acid	100 microgram
calcium pantothenate	109.17 mg
Equivalent: pantothenic acid	100 mg
choline dihydrogen citrate	56.5 mg
chromium nicotinate	400 microgram
Equivalent: chromium	50 microgram
Citrus bioflavonoids extract	22.22 mg
colecalfiferol	.0125 mg
hydroxocobalamin	350 microgram
iron (II) glycinate	18.2615 mg
Equivalent: iron	5 mg
levomefolate calcium	433.6 microgram
Equivalent: levomefolic acid	400 microgram
lutein	1 mg
manganese amino acid chelate	5 mg
Equivalent: manganese	500 microgram
mecobalamin (co-methylcobalamin)	150 microgram
menaquinone 7	25 microgram
mixed (low-alpha type) tocopherols concentrate	19.999 mg
molybdenum trioxide	90 microgram
Equivalent: molybdenum	60 microgram
nicotinamide	100 mg
potassium iodide	130 microgram
Equivalent: iodine	100 microgram
pyridoxal 5-phosphate monohydrate	31.35 mg
Equivalent: pyridoxine	20 mg
Reynoutria japonica root Extract dry concentrate standardised	20 mg
Equivalent: Reynoutria japonica (Dry)	1.6 g
riboflavin sodium phosphate	32.896 mg
Equivalent: riboflavin	25 mg
sodium selenate	179.4 microgram
Equivalent: selenium	75 microgram
thiamine hydrochloride	50 mg
Equivalent: thiamine	39.34 mg
zinc citrate dihydrate	46.73 mg
Equivalent: zinc	15 mg

Other Ingredients (Excipients)

Acacia
calcium hydrogen phosphate dihydrate
Carnauba Wax
citric acid
colloidal anhydrous silica
croscarmellose sodium
crospovidone
dl-alpha-tocopherol
hypromellose
liquid glucose
macrogol 400
maize starch

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maltodextrin
medium chain triglycerides
microcrystalline cellulose
Pea Starch
povidone
purified water
silicon dioxide
sodium alginate
sodium ascorbate
soluble maize starch
starch sodium octenyl succinate
stearic acid
sucrose

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