



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	301937	Fertility Formula Female
ARTG entry for	Medicine Listed	
Sponsor	Mygen Health Pty Ltd	
Postal Address	PO Box 4006, LANE COVE, NSW, 1595 Australia	
ARTG Start Date	17/04/2018	
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 . Fertility Formula Female

Product Type	Composite Pack	Effective Date	25/03/2019
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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
Aids/assists healthy bone development/growth/building
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
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 cardiovascular system health
Maintain/support healthy cardiovascular system function
Maintain/support blood capillary health
Maintain/support blood vessel health
Maintain/support healthy thyroid gland function in healthy adults
Maintain/support healthy thyroid gland function
Maintain/support healthy thyroid hormones in healthy adults
Maintain/support healthy thyroid hormones
Maintain/support thyroid gland health
Aid/assist thyroid hormone production in healthy adults
Maintain/support healthy liver function
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 when sun exposure is inadequate
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
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 nerve conduction
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support female reproductive system health
Helps maintains/support healthy foetal CNS/brain development
Maintains/support healthy foetal development
Maintain/support healthy pregnancy
Maintain/support maternal health
Maintain/support preconception health in healthy females
Maintain/support skin health
Maintain/support skin integrity/structure
Maintain/support skin regeneration
Maintain/support wound healing

Indication Requirements

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
Product presentation must not imply or refer to serious immunological diseases.

Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not



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replace a balanced diet.

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

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

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.

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

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

Product presentation must not imply or refer to heart disease.

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

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

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.

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 chronic fatigue syndrome.

Product presentation must not imply or refer to infertility.

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 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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Do not take while on warfarin therapy without medical advice.

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

This product 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.

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

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

betacarotene	3 mg
colecalfiferol	.025 mg
menaquinone 7	20 microgram
ubidecarenone	100 mg

Other Ingredients (Excipients)

- cochineal
- dl-alpha-tocopherol
- Gelatin
- glycerol

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hydrogenated vegetable oil
lecithin
medium chain triglycerides
purified water
Soya Oil
titanium dioxide
vegetable oil
yellow beeswax

2 . Formulation 2

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

alpha lipoic acid	100 mg
ascorbic acid	100 mg
Biotin	100 microgram
calcium pantothenate	54.59 mg
Equivalent: pantothenic acid	50 mg
choline bitartrate	486.26 mg
chromium nicotinate	500 microgram
Equivalent: chromium	50 microgram
d-alpha-tocopheryl acid succinate	200 mg
inositol	100 mg
iron (II) glycinate	19.22 mg
Equivalent: iron	5 mg
levomefolate calcium	542 microgram
Equivalent: levomefolic acid	500 microgram
manganese amino acid chelate	50 mg
Equivalent: manganese	5 mg
mecobalamin (co-methylcobalamin)	400 microgram
molybdenum trioxide	75 microgram
Equivalent: molybdenum	50 microgram
nicotinamide	75 mg
potassium iodide	294.3 microgram
Equivalent: iodine	225 microgram
pyridoxal 5-phosphate	15.38 mg
Equivalent: pyridoxine	10 mg
pyridoxine hydrochloride	60.73 mg
Equivalent: pyridoxine	50 mg
riboflavin	50 mg
selenomethionine	186 microgram
Equivalent: selenium	75 microgram
thiamine hydrochloride	56.06 mg
zinc citrate dihydrate	78.35 mg
Equivalent: zinc	25 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
calcium phosphate
Carnauba Wax
citric acid

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colloidal anhydrous silica
crospovidone
hypromellose
iron oxide black
iron oxide red
iron oxide yellow
macrogol 400
macrogol 8000
magnesium stearate
maltodextrin
microcrystalline cellulose
povidone
titanium dioxide

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