



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	351511	Fertility Formula Female
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Mygen Health Pty Ltd	
<b>Postal Address</b>	PO Box 4006, LANE COVE, NSW, 1595 Australia	
<b>ARTG Start Date</b>	10/12/2020	
<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 . Fertility Formula Female**

Product Type	Composite Pack	Effective Date	10/12/2020
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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
- 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

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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 mental illnesses, disorders or conditions.

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

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

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

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

Product presentation must not imply or refer to infertility.

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

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

Label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

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 heart disease.



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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.

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).

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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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

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

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

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

Do not take while on warfarin therapy without medical advice.

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.

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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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
- 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

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Route of Administration Oral

Visual Identification

Active Ingredients

<b>alpha lipoic acid</b>	<b>100 mg</b>
<b>ascorbic acid</b>	<b>100 mg</b>
<b>Biotin</b>	<b>100 microgram</b>
<b>calcium pantothenate</b>	<b>54.59 mg</b>
Equivalent: pantothenic acid	50 mg
<b>choline bitartrate</b>	<b>486.26 mg</b>
<b>chromium nicotinate</b>	<b>500 microgram</b>
Equivalent: chromium	50 microgram
<b>d-alpha-tocopheryl acid succinate</b>	<b>200 mg</b>
<b>inositol</b>	<b>100 mg</b>
<b>iron (II) glycinate</b>	<b>18.5 mg</b>
Equivalent: iron	5 mg
<b>levomefolate calcium</b>	<b>542 microgram</b>
Equivalent: levomefolic acid	500 microgram
<b>manganese amino acid chelate</b>	<b>50 mg</b>
Equivalent: manganese	5 mg
<b>mecobalamin (co-methylcobalamin)</b>	<b>400 microgram</b>
<b>nicotinamide</b>	<b>75 mg</b>
<b>potassium iodide</b>	<b>294 microgram</b>
Equivalent: iodine	225 microgram
<b>pyridoxal 5-phosphate</b>	<b>15.38 mg</b>
Equivalent: pyridoxine	10 mg
<b>pyridoxine hydrochloride</b>	<b>60.73 mg</b>
Equivalent: pyridoxine	50 mg
<b>riboflavin</b>	<b>50 mg</b>
<b>selenomethionine</b>	<b>186 microgram</b>
Equivalent: selenium	75 microgram
<b>sodium molybdate dihydrate</b>	<b>126 microgram</b>
Equivalent: molybdenum	50 microgram
<b>thiamine hydrochloride</b>	<b>56.06 mg</b>
<b>zinc citrate dihydrate</b>	<b>78.35 mg</b>
Equivalent: zinc	25 mg

Other Ingredients (Excipients)

calcium carbonate  
calcium hydrogen phosphate dihydrate  
calcium hydrogen phosphate  
calcium phosphate  
citric acid  
colloidal anhydrous silica  
crospovidone  
hypromellose  
iron oxide black  
iron oxide red  
iron oxide yellow  
macrogol 400  
magnesium stearate  
maltodextrin

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microcrystalline cellulose

potable water

povidone

purified water

silicon dioxide

titanium dioxide

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