Public Summary

Summary for ARTG Entry:	315307	Maternity Formula
ARTG entry for	Medicine Listed	
Sponsor	Mygen Health Pty Ltd	
Postal Address	PO Box 4006, LANE COVE, NSW, 1595 Australia	
ARTG Start Date	12/03/2019	
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 . Maternity Formula

Product Type	Composite Pack	**Effective Date**	10/04/2019

Permitted Indications

Helps maintains/support healthy foetal CNS/brain development

Enhance/promote healthy foetal development

Maintains/support healthy foetal development

Maintain/support healthy pregnancy

Helps enhance/promote maternal health

Maintain/support maternal health

Indication Requirements

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

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

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.

Do not take while on warfarin therapy without medical advice.

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

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Multiple containers	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

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

ascorbic acid	**200 mg**
betacarotene	**3 mg**
Biotin	**100 microgram**
calcium pantothenate	**22.22 mg**
Equivalent: pantothenic acid	20 mg
choline bitartrate	**417.9 mg**
chromium picolinate	**403.25 microgram**
Equivalent: chromium	50 microgram
iron (II) glycinate	**38.44 mg**
Equivalent: iron	10 mg
levomefolate calcium	**542 microgram**
Equivalent: levomefolic acid	500 microgram
manganese sulfate monohydrate	**15.38 mg**
Equivalent: manganese	5 mg
mecobalamin (co-methylcobalamin)	**200 microgram**
nicotinamide	**20 mg**
potassium iodide	**294.3 microgram**
Equivalent: iodine	225 microgram
pyridoxal 5-phosphate monohydrate	**10 mg**
Equivalent: pyridoxine	6.4 mg
pyridoxine hydrochloride	**60.78 mg**
Equivalent: pyridoxine	50 mg
riboflavin	**20 mg**
selenomethionine	**186 microgram**
Equivalent: selenium	75 microgram
thiamine hydrochloride	**22.66 mg**
ubidecarenone	**75 mg**
zinc citrate dihydrate	**78.13 mg**
Equivalent: zinc	25 mg

Other Ingredients (Excipients)

ascorbyl palmitate
calcium hydrogen phosphate dihydrate
calcium phosphate
Carnauba Wax
citric acid

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colloidal anhydrous silica
crospovidone
dl-alpha-tocopherol
Gelatin
hypromellose
iron oxide black
iron oxide red
iron oxide yellow
macrogol 400
magnesium stearate
maize starch
maltodextrin
microcrystalline cellulose
potable water
povidone
sodium ascorbate
sucrose
titanium dioxide

2 . Formulation 2

Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients	
calcium citrate tetrahydrate	**711.71 mg**
Equivalent: calcium	150 mg
colecalciferol	**.0125 mg**
magnesium citrate	**483.6 mg**
Equivalent: magnesium	75 mg
menaquinone 7	**20 microgram**

Other Ingredients (Excipients)

Acacia
calcium hydrogen phosphate dihydrate
Carnauba Wax
colloidal anhydrous silica
crospovidone
dl-alpha-tocopherol
hypromellose
macrogol 400
magnesium stearate
maize starch
maltodextrin
medium chain triglycerides
microcrystalline cellulose
povidone
silicon dioxide
sucrose
titanium dioxide

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