



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	295927	Facia Premium
ARTG entry for	Medicine Listed	
Sponsor	Contract Manufacturing & Packaging Services Pty Ltd	
Postal Address	20 - 22 Long Street, SMITHFIELD, NSW, 2164 Australia	
ARTG Start Date	6/11/2017	
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 . Facia Premium

Product Type	Single Medicine Product	Effective Date	6/09/2019
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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 natural liver cleansing/detoxification processes
- 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 health
- Maintain/support healthy teeth
- Decrease/reduce nail brittleness/splitting/chipping in females
- Maintain/support nail health/strength/thickness
- Enhance/improve/promote/increase nail health/strength/thickness in females
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support bone health

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Aids/assists healthy bone development/growth/building
Maintain/support blood capillary health
Maintain/support blood vessel health
Maintain/support immune system health
Maintain/support healthy immune 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)
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 nervous system function
Maintain/support female reproductive system health
Maintain/support preconception health in healthy females
Maintain/support healthy reproductive hormones
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 circulatory disorders/diseases/conditions e.g. thrombosis.

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

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 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 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.

Product presentation must not imply or refer to drugs/alcohol.

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).

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

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

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 only refer to detoxification in relation to natural body processes.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Product presentation must not imply or refer to hormone imbalances.

Product presentation must not imply or refer to infertility.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only.
Not recommended for use by pregnant and lactating women (or words to that effect).



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Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Multiple containers	Not recorded	Not recorded	Not recorded	Neither child resistant closure nor restricted flow insert	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	15 mg
Biotin	5 mg
calcium pantothenate	25 mg
chromic chloride hexahydrate	50 microgram
Equivalent: chromium	9.75 microgram
colloidal anhydrous silica	11 mg
Equivalent: silicon	5.14 mg
demineralised fish proteoglycan extract	25 mg
Equisetum arvense stem Extract dry concentrate standardised	40 mg
Equivalent: Equisetum arvense (Dry)	160 mg
glutathione	250 mg
lycopene	.1 mg
manganese amino acid chelate	20 mg
Equivalent: manganese	2 mg
Vitis vinifera seed Extract dry concentrate	5 mg
Equivalent: Vitis vinifera (Dry)	600 mg
zinc amino acid chelate	25 mg
Equivalent: zinc	5 mg

Other Ingredients (Excipients)

- Acacia
- brilliant blue FCF
- calcium hydrogen phosphate dihydrate
- carmoisine
- Collagen
- croscarmellose sodium
- Gelatin
- magnesium stearate
- maltodextrin
- medium chain triglycerides
- Pisum sativum
- purified water
- quinoline yellow
- sodium alginate
- sodium lauryl sulfate
- titanium dioxide

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