



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	327280	Ultra Potent-C
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Level 4 / 64 Kippax Street, Surry Hills, NSW, 2010 Australia	
ARTG Start Date	10/12/2019	
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.

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 . Ultra Potent-C

Product Type	Single Medicine Product	Effective Date	23/02/2021
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Maintain/support collagen formation
Maintain/support energy levels
Maintain/support energy production
Relieve weariness/tiredness/fatigue/feeling of weakness
Maintain/support healthy immune system function
Maintain/support immune system to fight illness
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Aid/assist/helps synthesis of neurotransmitters
Maintain/support sperm health
Maintain/support wound healing

Indication Requirements

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

Standard Indications

No Standard Indications included on Record

Specific Indications



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No Specific Indications included on Record

Warnings

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

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Powder
Route of Administration	Oral

Visual Identification

Active Ingredients

ascorbic acid	450 mg/g
calcium ascorbate dihydrate	54.5 mg/g
Equivalent: ascorbic acid	45 mg/g
d-alpha-tocopheryl acid succinate	20.76 mg/g
Dunaliella salina cell Extract soft concentrate standardised	15 mg/g
Equivalent: Dunaliella salina (Fresh)	9.375 mg/g
rutoside	19.5 mg/g
sodium ascorbate	132.17 mg/g
Equivalent: ascorbic acid	117.5 mg/g
zinc amino acid chelate	6.25 mg/g
Equivalent: zinc	1.25 mg/g

Other Ingredients (Excipients)

Acacia
ascorbic acid
ascorbyl palmitate
citric acid
colloidal anhydrous silica
d-alpha-tocopherol
ethylcellulose
Flavour
maltodextrin
Olive Oil
povidone
purified water
silicon dioxide
sodium bicarbonate
Stevia rebaudiana

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