



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:		208690	Ultra Potent-C Chewables
ARTG entry for	Medicine Listed		
Sponsor	FIT-BioCeuticals Pty Ltd		
Postal Address	Level 4 / 64 Kippax Street, Surry Hills, NSW, 2010 Australia		
ARTG Start Date	23/04/2013		
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 Chewables

Product Type	Single Medicine Product	Effective Date	17/09/2025
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body in children
Antioxidant/Reduce free radicals formed in the body
Antioxidant/Reduce free radicals formed in the body in children over 12 years of age
Maintain/support collagen formation
Maintain/support collagen formation in children over 12 years of age
Maintain/support collagen formation in children
Maintain/support energy levels
Maintain/support energy levels in children over 12 years of age
Maintain/support energy levels in children
Maintain/support energy production in children over 12 years of age
Maintain/support energy production in children
Maintain/support energy production
Relieve weariness/tiredness/fatigue/feeling of weakness
Relieve weariness/tiredness/fatigue/feeling of weakness in children over 12 years of age
Relieve weariness/tiredness/fatigue/feeling of weakness in children
Maintain/support healthy immune system function in children
Maintain/support healthy immune system function in children over 12 years of age
Maintain/support healthy immune system function
Maintain/support immune system to fight illness
Maintain/support immune system to fight illness in children
Maintain/support immune system to fight illness in children over 12 years of age
Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in children
Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in children over 12 years of age
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Maintain/support (state vitamin/mineral/nutrient) levels in the body in children
Maintain/support (state vitamin/mineral/nutrient) levels in the body in children over 12 years of age



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Maintain/support sperm health
Maintain/support wound healing
Maintain/support wound healing in children over 12 years of age
Maintain/support wound healing in children

Indication Requirements

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

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 serious immunological diseases.

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 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).

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

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Tablet, chewable
Route of Administration	Oral

Visual Identification

Active Ingredients

ascorbic acid	735 mg
betacarotene	.375 mg
d-alpha-tocopheryl acid succinate	15.97 mg
rutoside trihydrate	19.5 mg
sodium ascorbate	298.09 mg
Equivalent: ascorbic acid	265 mg
zinc gluconate	38.29 mg
Equivalent: zinc	5 mg

Other Ingredients (Excipients)

carmellose sodium
colloidal anhydrous silica
dl-alpha-tocopherol
ethylcellulose
Flavour
hypromellose
iron oxide red
iron oxide yellow
magnesium stearate
maize starch



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mannitol
povidone
purified water
starch sodium octenyl succinate
Stevia rebaudiana
Steviol glycosides
xylitol

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