



**Australian Government**  
**Department of Health**  
**Therapeutic Goods Administration**

## Public Summary

<b>Summary for ARTG Entry:</b>	385054	Ultra Potent-C
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	FIT-BioCeuticals Limited	
<b>Postal Address</b>	Level 4 / 64 Kippax Street, Surry Hills, NSW, 2010 Australia	
<b>ARTG Start Date</b>	3/03/2022	
<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 . Ultra Potent-C

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	3/03/2022
---------------------	-------------------------	-----------------------	-----------

### 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 chronic fatigue syndrome.

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 serious immunological diseases.

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 infertility.

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.

### Standard Indications

No Standard Indications included on Record

### Specific Indications



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

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
-----------	-----------------

##### Components

###### 1 . Formulation 1

Dosage Form	Powder
Route of Administration	Oral

###### Visual Identification

##### Active Ingredients

ascorbic acid	450 mg/g
betacarotene	.375 mg/g
calcium ascorbate dihydrate	54.5 mg/g
Equivalent: ascorbic acid	45 mg/g
d-alpha-tocopheryl acid succinate	20.76 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  
citric acid  
colloidal anhydrous silica  
dl-alpha-tocopherol  
Flavour  
maltodextrin  
medium chain triglycerides  
povidone  
silicon dioxide  
sodium ascorbate  
sodium bicarbonate  
spray-dried glucose syrup  
starch sodium octenyl succinate  
Stevia rebaudiana  
sucrose

Public Summary

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.