Public Summary

Summary for ARTG Entry:	208690 Ultra Potent-C Chewables
ARTG entry for	Medicine Listed
Sponsor	FIT-BioCeuticals Limited
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 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.

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 . Ultra Potent-C Chewables

Product Type	Single Medicine Product	**Effective Date**	3/10/2019

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 in children over 12 years of age
Maintain/support collagen formation
Maintain/support collagen formation in children
Maintain/support energy levels
Maintain/support energy levels in children
Maintain/support energy levels in children over 12 years of age
Maintain/support energy production
Maintain/support energy production in children over 12 years of age
Maintain/support energy production in children
Relieve weariness/tiredness/fatigue/feeling of weakness in children
Relieve weariness/tiredness/fatigue/feeling of weakness in children over 12 years of age
Relieve weariness/tiredness/fatigue/feeling of weakness
Maintain/support healthy immune system function in children over 12 years of age
Maintain/support healthy immune system function in children
Maintain/support healthy immune system function
Maintain/support immune system to fight illness

Maintain/support immune system to fight illness in children over 12 years of age

Maintain/support immune system to fight illness in children

Maintain/support absorption of dietary (state vitamin/mineral/nutrient)

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) in children

Maintain/support (state vitamin/mineral/nutrient) levels in the body in breastfeeding women

Maintain/support (state vitamin/mineral/nutrient) levels in the body in children

Maintain/support (state vitamin/mineral/nutrient) levels in the body

Maintain/support (state vitamin/mineral/nutrient) levels in the body in children over 12 years of age

Maintains/support healthy foetal development

Maintain/support sperm health

Maintain/support wound healing

Maintain/support wound healing in children

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

Indication Requirements

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.

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.

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 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 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

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