



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	281420	AntiOx Excel
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	17/10/2016	
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.

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 . AntiOx Excel

Product Type	Single Medicine Product	Effective Date	12/05/2020
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps convert (state food) into energy
Maintain/support general health and wellbeing
Anti-inflammatory/relieve inflammation
Maintain/support skin health

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.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

Adults only.

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

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.



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Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

alpha lipoic acid	20 mg
ascorbic acid	30.07 mg
ascorbyl palmitate	45 mg
Equivalent: ascorbic acid	19.12 mg
calcium ascorbate dihydrate	125.52 mg
Equivalent: ascorbic acid	103.7 mg
Dunaliella salina	13.34 mg
glutathione	50 mg
Lycopersicon esculentum	8.33 mg
nicotinamide	20 mg
palm tocotrienols complex	20 mg
Equivalent: alpha-tocotrienol (of palm tocotrienols complex)	900 microgram
retinol acetate	.3001 mg
Reynoutria japonica root Extract dry concentrate standardised	225 mg
Equivalent: Reynoutria japonica (Dry)	22.5 g
riboflavin	5 mg
selenomethionine	248.6 microgram
Equivalent: selenium	100 microgram
Silybum marianum fruit Extract dry concentrate standardised	18.75 mg
Equivalent: Silybum marianum (Dry)	1.3125 g
Vaccinium myrtillus fruit Extract dry concentrate	1 mg
Equivalent: Vaccinium myrtillus (Fresh)	100 mg
Vitis vinifera seed Extract dry concentrate standardised	60.42 mg
Equivalent: Vitis vinifera (Dry)	7.25 g
zinc citrate dihydrate	15.57 mg
Equivalent: zinc	5 mg

Other Ingredients (Excipients)

ascorbyl palmitate
 butylated hydroxytoluene
 calcium hydrogen phosphate dihydrate
 colloidal anhydrous silica
 croscarmellose sodium
 Gelatin
 hypromellose
 magnesium stearate
 maize starch
 microcrystalline cellulose
 mixed (low-alpha type) tocopherols concentrate
 potable water
 pregelatinised maize starch

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purified water
silicon dioxide
Soya Oil
sucrose
tartaric acid

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