



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

## Public Summary

<b>Summary for ARTG Entry:</b>	379813	AntiOx Excel
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	FIT-BioCeuticals Limited	
<b>Postal Address</b>	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
<b>ARTG Start Date</b>	1/12/2021	
<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 . AntiOx Excel

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	1/12/2021
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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

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

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

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

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.

Adults only.

#### Additional Product information

#### Pack Size/Poison information



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Pack Size

Poison Schedule

**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>alpha lipoic acid</b>	<b>20 mg</b>
<b>ascorbic acid</b>	<b>30.07 mg</b>
<b>ascorbyl palmitate</b>	<b>45 mg</b>
Equivalent: ascorbic acid	19.12 mg
<b>betacarotene</b>	<b>2.668 mg</b>
<b>calcium ascorbate dihydrate</b>	<b>125.52 mg</b>
Equivalent: ascorbic acid	103.7 mg
<b>glutathione</b>	<b>50 mg</b>
<b>Lycopersicon esculentum fruit Extract soft concentrate standardised</b>	<b>8.33 mg</b>
Equivalent: Lycopersicon esculentum (Fresh)	2915.5 mg
<b>nicotinamide</b>	<b>20 mg</b>
<b>palm tocotrienols complex</b>	<b>20 mg</b>
Equivalent: alpha-tocotrienol (of palm tocotrienols complex)	900 microgram
<b>retinol acetate</b>	<b>.3001 mg</b>
Equivalent: vitamin A	.261 mg
<b>Reynoutria japonica root Extract dry concentrate standardised</b>	<b>225 mg</b>
Equivalent: Reynoutria japonica (Dry)	22.5 g
<b>riboflavin</b>	<b>5 mg</b>
<b>selenomethionine</b>	<b>248.6 microgram</b>
Equivalent: selenium	100 microgram
<b>Silybum marianum fruit Extract dry concentrate standardised</b>	<b>18.75 mg</b>
Equivalent: Silybum marianum (Dry)	1.3125 g
<b>Vaccinium myrtillus fruit Extract dry concentrate</b>	<b>1 mg</b>
Equivalent: Vaccinium myrtillus (Fresh)	100 mg
<b>Vitis vinifera seed Extract dry concentrate standardised</b>	<b>60.42 mg</b>
Equivalent: Vitis vinifera (Dry)	7.25 g
<b>zinc citrate dihydrate</b>	<b>15.57 mg</b>
Equivalent: zinc	5 mg

**Other Ingredients (Excipients)**

**Acacia**

**butylated hydroxytoluene**

**calcium hydrogen phosphate dihydrate**

**colloidal anhydrous silica**

**croscarmellose sodium**

**Gelatin**

**hypromellose**

**magnesium stearate**

**maize starch**

**microcrystalline cellulose**

**Pea Starch**

**pregelatinised maize starch**

**purified water**

**silicon dioxide**

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**sodium alginate**

**sucrose**

**tartaric acid**

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