

ANNEXURE J

Allowable levels and claims: Carotenoids

Note:

Any claims provided may be used with any of the stipulated dosage ranges.

Minimum: Minimum Daily Levels Required for use of Health Supplement Claim

Maximum: Maximum Daily Levels Permitted as Health Supplement

SSF: Single substance formulation

MSF: Multiple substance formulation

Unless otherwise stated the dosage form is oral.

Carotenoids are divided into the following categories:

- A. Carotenoids with **Pro-Vitamin A activity**.
- B. Carotenoids mainly used as **Anti-oxidants**.

The maximum daily dose for these Carotenoids in combination with other vitamin A source materials must not exceed the maximum daily dose for vitamin A indicated in Annexure E.

Carotenoids may be derived from the listed source materials but must be substantially pure extracts from the source material and not simply the inclusion of the source material as a whole.

Action: Source of Pro-vitamin A OR antioxidants.

General Statements:

Requirement for labelling:

If you are pregnant or breast feeding your baby please consult your doctor, pharmacist or other registered health care practitioner for advice before taking this medicine.

Registration of Medicines

Health Supplements

Store in airtight container, protected from light.

Do not exceed daily dosage level without consulting a registered healthcare practitioner.

Long term users (3-month continuous use) should be evaluated and practiced under the care of a registered healthcare practitioner.

Duration of Use:

If more than one duration of use statement is indicated for a particular product formulation, only the shortest applicable duration of use statement is required on the labelling.

Carotenoid	Health Supplement Claim	Specified Warning(s)	Dosage <i>RE: Retinol Equivalents</i>	
			Minimum	Maximum
A. Carotenoids with Pro-Vitamin A activity				
<p>β-Carotene <i>(all-E)-1,1'-(3,7,12,16 Tetramethyl-1,3,5,7,9,11,13,15,17-octadecanonaene-1,18-diy)bis[2,6,6-trimethylcyclohexen. All-trans beta carotene Beta carotene</i></p> <p>Sources: <i>All-trans-beta-carotene Beta-carotene</i></p>	<p>Provitamin A;</p> <ul style="list-style-type: none"> - for the maintenance of good health. - to help maintain eyesight, skin, membranes and immune function. - to help in the development and maintenance of night vision. - to help in the development and maintenance of bones and teeth. - Maintain / Support healthy vitamin A levels. 	<p>Consult a health care practitioner prior to use if you are a tobacco smoker, have cardiovascular disease, or use statins to lower cholesterol.</p>	<p>Calculated to yield Retinal Activity Equivalents not exceeding dosages as stipulated in Annexure E, Vitamin A.</p>	
<p>α-Carotene <i>(all-E)-1,3,3-Trimethyl-2-(3,7,12,1-tetramethyl-18-(2,6,6-trimethyl-2-cyclohexen-1-yl)-1,3,5,7,9,11,13,15,17-octadecanonaenyl)cyclohexene</i></p> <p>Sources: <i>Citrus sinensis (Fruit); Dunaliella salina (Whole); Elaeis guineensis (Branch); Elaeis guineensis (Fruit); Persea americana (Fruit); Rubus idaeus (Fruit); Solanum lycopersicum (Fruit); Zea mays (Seed)</i></p>	<p><i>As per Annexure E, Vitamin A.</i></p> <p>Source of antioxidant(s)/Provides antioxidant(s).</p>		<p>Calculated to yield Retinal Activity Equivalents (RAE) not exceeding dosages as stipulated in Annexure E, Vitamin A.</p>	
<p>Cryptoxanthin <i>(3R)-beta,beta-Caroten-3-ol beta-Caroten-3-ol Cryptoxanthine Kryptoxanthin</i></p> <p>Sources: <i>Capsicum annuum (Fruit); Capsicum annuum (Petal); Carica papaya (Fruit); Citrus aurantium (Fruit peel); Citrus limon (Fruit peel); Citrus paradisi (Fruit); Citrus paradisi (Fruit peel); Citrus sinensis (Fruit peel); Dunaliella salina (Whole); Persea americana (Fruit); Prunus persica (Whole plant); Tagetes erecta (Flower); Zea mays (Seed)</i></p>	<p><i>As per Annexure E, Vitamin A.</i></p> <p>Source of antioxidant(s)/Provides antioxidant(s).</p>		<p>Calculated to yield Retinal Activity Equivalents not exceeding dosages as stipulated in Annexure E, Vitamin A.</p>	

Carotenoid	Health Supplement Claim	Specified Warning(s)	Dosage	
			Minimum	Maximum
B. Carotenoids mainly used as Anti-oxidants				
<p>Astaxanthin 3,3'-dihydroxy-4,4'-diketo-beta-carotene. 3,3'-Dihydroxy-beta,beta-carotene-4,4'-dione</p> <p>Sources: <i>Haematococcus pluvialis (Whole);</i> <i>Pandalus borealis (Internal shell)</i></p>	<p>Source of antioxidant(s)/Provides antioxidant(s).</p> <p>Antioxidant that helps fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals.</p>	<p>Not suitable for children.</p> <p>Use should be avoided when taking immunosuppressants, by patients with bleeding disorders, and by patients on 5-α-reductase inhibitors.</p> <p>Astaxanthin > 4 mg per day: For use beyond 3 months, consult a registered health care practitioner.</p>	4 mg	8 mg
<p>Lycopene All-trans-lycopene Lycopene psi,psi-Carotene CI 75125 E160(d) Natural yellow 27</p> <p>Sources: Tomato extract; <i>Blakeslea trispora (Whole);</i> <i>Citrullus lanatus var. lanatus (Fruit);</i> <i>Citrus aurantium (Fruit);</i> <i>Citrus limon (Fruit);</i> <i>Citrus paradisi (Fruit);</i> <i>Citrus sinensis (Fruit);</i> <i>Elaeis guineensis (Fruit);</i> <i>Rosa canina (Fruit);</i> <i>Solanum lycopersicum (Fruit);</i> <i>Solanum lycopersicum (Fruit flesh)</i></p>	<p>Source of antioxidant(s)/Provides antioxidant(s).</p> <p>Antioxidant that helps fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals.</p> <p><i>For products providing at least 6,5 mg per day:</i> Helps to support prostate health.</p>	<p>Not suitable for children.</p> <p>Consult a registered healthcare practitioner prior to use if diagnosed or suspected to suffer from prostate cancer.</p>	<i>Annexure B submission required.</i>	20 mg
<p>Lutein (3R,3'R,6'R)-beta,epsilon-Carotene-3,3'-diol (3R,3'R,6'R)-beta,epsilon-Carotene-3,3'-diol CI 75125 E161(b) Mixed carotenoids (comprising xanthophylls and zeaxanthin) Vegetable lutein Vegetable luteol Xanthophylls</p>	<p>Antioxidant for the maintenance of good health/eye health.</p> <p>Antioxidant that helps fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals.</p> <p><i>For products providing at least 6 mg per day:</i> Helps to maintain/support eyesight in certain conditions (associated with sunlight damage). Helps to improve macular pigment optical density.</p>		<i>Annexure B submission required.</i>	6 mg

Carotenoid	Health Supplement Claim	Specified Warning(s)	Dosage	
			Minimum	Maximum
B. Carotenoids mainly used as Anti-oxidants				
Sources: Oleoresin from the flower of marigold (<i>Tagetes erecta</i> L.(Asteraceae)); <i>Arnica montana</i> (Flower); <i>Capsicum annuum</i> (Fruit); <i>Cucurbita pepo</i> (Flower); <i>Fucus vesiculosus</i> (Whole); <i>Oryza sativa</i> (Whole plant); <i>Pisum sativum</i> (Whole plant); <i>Solanum lycopersicum</i> (Fruit); <i>Tagetes erecta</i> (Flower); <i>Tagetes erecta</i> (Herb flowering oleoresin); <i>Tagetes erecta</i> (Petal); <i>Taraxacum officinale</i> (Flower); <i>Tussilago farfara</i> (Flower); <i>Viscum album</i> (Leaf)				
Lutein Esters Sources: Oleoresin from the flower of marigold (<i>Tagetes erecta</i> L.(Asteraceae))	As for Lutein.	As for Lutein.	As for Lutein.	
Zeaxanthin (3R,3'R)-beta,beta-Carotene-3,3'-diol All-trans-beta-Carotene-3,3'-diol Anchovyxanthin beta-Carotene-3,3'-diol meso-zeaxanthin Zeaxanthol	Antioxidant for the maintenance of good health / eye health. For products providing at least 0,7 mg per day: Helps to maintain eyesight in conditions (associated with sunlight damage). Helps to improve macular pigment optical density.		Annexure B submission required.	2,5 mg (Total from all sources)
Sources: Oleoresin from the flower of marigold (<i>Tagetes erecta</i> L.(Asteraceae)); <i>Arnica montana</i> (Flower); <i>Asparagus officinalis</i> (Whole plant); <i>Berberis vulgaris</i> (Whole plant); <i>Camellia sinensis</i> (Leaf); <i>Capsicum annuum</i> (Fruit); <i>Capsicum frutescens</i> (Fruit); <i>Carica papaya</i> (Fruit); <i>Citrus aurantiifolia</i> (Fruit); <i>Citrus aurantium</i> (Fruit); <i>Citrus bergamia</i> (Fruit); <i>Citrus limon</i> (Leaf); <i>Citrus medica</i> var. <i>sarcodactylis</i> (Fruit); <i>Citrus paradisi</i> (Fruit); <i>Citrus reticulata</i> (Fruit); <i>Citrus sinensis</i> (Fruit); <i>Crocus sativus</i> (Peta); <i>Crocus sativus</i> (Stigma and style); <i>Cucurbita pepo</i> (Flower); <i>Dunaliella salina</i> (Whole); <i>Eschscholzia californica</i> (Whole plant); <i>Fucus vesiculosus</i> (Whole); <i>Hippophae rhamnoides</i> (Fruit); <i>Lycium chinense</i> (Fruit); <i>Medicago sativa</i> (Whole plant); <i>Momordica charantia</i> (Fruit); <i>Nannochloropsis gaditana</i> (Broken cell); <i>Palmaria palmata</i> (Whole plant); <i>Prunus persica</i> (Fruit); <i>Rosa canina</i> (Fruit); <i>Solanum lycopersicum</i> (Fruit); <i>Tagetes erecta</i> (Flower); <i>Tagetes erecta</i> (Herb flowering oleoresin); <i>Zea mays</i> (Seed); <i>Zea mays</i> (Whole plant)				
Zeaxanthin Esters Sources: Oleoresin from the flower of marigold (<i>Tagetes erecta</i> L.(Asteraceae))	Antioxidant for the maintenance of good health / eye health. For products providing at least 1,5 mg per day: Helps to maintain eyesight in conditions (associated with sunlight damage). Helps to improve macular pigment optical density.		Annexure B submission required.	5 mg (Total from all sources)