



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	370237	Cognisense Pro
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	25/06/2021	
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.

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 . Cognisense Pro

Product Type	Single Medicine Product	Effective Date	25/06/2021
---------------------	-------------------------	-----------------------	------------

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support energy production
- Helps maintain/support healthy vision development
- Maintain/support healthy growth and development
- Maintain/support body mucous membrane health
- Maintain/support general health and wellbeing
- Maintain/support hair growth
- Maintain/support hair health
- Maintain/support healthy teeth
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Maintain/support bone mass/density/integrity
- Maintain/support (state mineral) absorption in bones
- Help maintain/support bone mineralisation
- Maintain/support healthy thyroid gland function
- Maintain/support thyroid gland health
- Maintain/support smell sensation
- Maintain/support taste sensation
- Maintain/support healthy mucous linings of the digestive system
- Maintain/support gastrointestinal mucosal membrane health
- Aids/assists repair of gastrointestinal/gut wall lining
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support immune system to fight illness
- Maintain/support healthy neuromuscular system/function
- Helps decrease/reduce homocysteine levels in healthy individuals

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Maintain/support (state vitamin/mineral/nutrient) levels in the body
Support healthy stress response in the body
Decrease/reduce/relieve symptoms of mild anxiety
Maintain/support cognitive function/mental function in children
Maintain/support cognitive function/mental function
Maintain/support learning and information processing
Maintain/support learning and information processing in children
Maintain/support memory/mental recall in children
Maintain/support memory/mental recall
Maintain/support brain function in children
Maintain/support brain function
Maintain/support brain health in children
Maintain/support brain health
Maintain/support nerve conduction
Maintain/support neuromuscular function
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support brain/central nervous system development
Maintain/support nervous system function
Maintain/support healthy mucous membranes/mucous tissue of the respiratory tract
Maintain/support skin health
Maintain/support skin integrity/structure
Maintain/support wound healing in healthy individuals
Maintain/support skin repair/healing/regeneration in healthy individuals

Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to any thyroid related diseases.
Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.
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).
Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
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 musculoskeletal or neurological conditions.
Product presentation must only refer to mild anxiety.
Product presentation must not imply or refer to neurological conditions or developmental delays.

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.
If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.
Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.
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.
The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

Additional Product information



Australian Government
Department of Health
 Therapeutic Goods Administration

Pack Size/Poison information

Pack Size	Poison Schedule
-----------	-----------------

Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

acetyl levocarnitine hydrochloride	41.67 mg/g
calcium citrate	69.16 mg/g
Equivalent: calcium	16.67 mg/g
calcium folinate	36.1 microgram/g
Equivalent: folic acid	33.3 microgram/g
calcium pantothenate	3.33 mg/g
Equivalent: pantothenic acid	3.05 mg/g
choline bitartrate	58.35 mg/g
Equivalent: choline	24 mg/g
colecalfiferol	.0041 mg/g
glycine	333.33 mg/g
hydroxocobalamin	33.3 microgram/g
inositol	83.33 mg/g
lecithin	16.67 mg/g
Equivalent: phosphatidyl choline	3.33 mg/g
magnesium citrate	140.26 mg/g
Equivalent: magnesium	21.67 mg/g
menaquinone 7	5.8 microgram/g
molybdenum trioxide	5.5 microgram/g
Equivalent: molybdenum	3.7 microgram/g
nicotinamide	2.5 mg/g
Pinus radiata stem bark Extract dry concentrate	8.34 mg/g
Equivalent: Pinus radiata (Dry)	834 mg/g
potassium citrate	34.57 mg/g
Equivalent: potassium	12.5 mg/g
Punica granatum seed Extract dry concentrate	1.34 mg/g
Equivalent: Punica granatum (Dry)	67 mg/g
pyridoxal 5-phosphate monohydrate	2.62 mg/g
Equivalent: pyridoxine	1.67 mg/g
retinol acetate	76.843 microgram/g
Equivalent: vitamin A	65.1495 microgram/g
riboflavin sodium phosphate	1.09 mg/g
Equivalent: riboflavin	.83 mg/g
selenomethionine	12.4 microgram/g
Equivalent: selenium	5 microgram/g
taurine	83.33 mg/g
thiamine hydrochloride	2.12 mg/g
Equivalent: thiamine	1.67 mg/g
Vaccinium myrtillus fruit Extract dry concentrate	416.7 microgram/g
Equivalent: Vaccinium myrtillus (Fresh)	41.67 mg/g
zinc citrate dihydrate	5.2 mg/g



Australian Government
Department of Health
Therapeutic Goods Administration

Equivalent: zinc

1.67 mg/g

Other Ingredients (Excipients)

Acacia
Beta vulgaris
citric acid
colloidal anhydrous silica
dl-alpha-tocopherol
Flavour
glycine
maize starch
maltodextrin
medium chain triglycerides
silicon dioxide
Siraitia grosvenorii
spray-dried glucose syrup
Stevia rebaudiana
sucrose

© 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>.

Public Summary