



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	342946	Repairase
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Bio Concepts Pty Ltd	
<b>Postal Address</b>	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
<b>ARTG Start Date</b>	3/09/2020	
<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 . Repairase

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	6/11/2020
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#### Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support collagen formation
- Maintain/support natural liver cleansing/detoxification processes
- Maintain/support energy production
- Maintain/support eye health
- Aids/assists eye adaption to variations in light intensity/night vision
- Helps maintain/support healthy vision development
- Maintain/support healthy eyesight/vision
- Maintain/support healthy growth and development
- Maintain/support body mucous membrane health
- Maintain/support general health and wellbeing
- Maintain/support healthy teeth
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Helps maintain/support joint cartilage health
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Maintain/support blood capillary health
- Maintain/support healthy thyroid hormones
- Aid/assist thyroid hormone production
- Maintain/support smell sensation
- Maintain/support taste sensation

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Maintain/support healthy digestive system function  
Maintain/support healthy mucous linings of the digestive system  
Maintain/support gastrointestinal mucosal membrane health  
Aids/assists repair of gastrointestinal/gut wall lining  
Relieve digestive discomfort  
Maintain/support bile production  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Maintain/support immune system to fight illness  
Aid/assist/helps protein synthesis in the body  
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)  
Maintain/support (state vitamin/mineral/nutrient) levels in the body  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)  
Support healthy stress response in the body  
Aid/assist/helps synthesis of neurotransmitters  
Maintain/support nervous system health  
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 circulatory disorders/diseases/conditions e.g. thrombosis.

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.

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 any form of arthritis or osteoarthritis unless qualified as mild.

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

Product presentation must only refer to detoxification in relation to natural body processes.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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 any thyroid related diseases.

Product presentation must not imply or refer to serious cardiovascular conditions.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Product presentation must not imply or refer to serious immunological diseases.

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

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

Product presentation must not imply or refer to drugs/alcohol.

Product presentation must not imply or refer to neurological conditions or developmental delays.

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.

**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.



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If symptoms persist consult your healthcare practitioner (or words to that effect).

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

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.

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

**Additional Product information**

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Powder, oral

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>bromelains</b>	<b>.48 million PU/g</b>
<b>calcium pantothenate</b>	<b>35.18 mg/g</b>
Equivalent: pantothenic acid	32.23 mg/g
<b>d-alpha-tocopheryl acid succinate</b>	<b>64.52 mg/g</b>
Equivalent: d-alpha-tocopheryl acid succinate	78.06 IU/g
<b>magnesium ascorbate monohydrate</b>	<b>307.32 mg/g</b>
Equivalent: ascorbic acid	274.2 mg/g
<b>quercetin dihydrate</b>	<b>144.41 mg/g</b>
Equivalent: quercetin	129 mg/g
<b>retinol acetate</b>	<b>.2852 mg/g</b>
<b>rutoside</b>	<b>161.29 mg/g</b>
<b>selenomethionine</b>	<b>10.4 microgram/g</b>
Equivalent: selenium	4.2 microgram/g
<b>zinc gluconate</b>	<b>9.49 mg/g</b>
Equivalent: zinc	1.29 mg/g

**Other Ingredients (Excipients)**

**Acacia**  
**citric acid**  
**dl-alpha-tocopherol**  
**Flavour**  
**glycine**  
**maize starch**  
**malic acid**  
**spray-dried glucose syrup**  
**Stevia rebaudiana**

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