



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

## Public Summary

<b>Summary for ARTG Entry:</b>	328164	Floradix Epresat Liquid Multi
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Endeavour CH Pty Ltd	
<b>Postal Address</b>	Endeavour Consumer Health, Level 7 737 Bourke St, Docklands, VIC, 3008 Australia	
<b>ARTG Start Date</b>	2/01/2020	
<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 . Floradix Epresat Liquid Multi

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	27/08/2021
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### Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support collagen formation
- Maintain/support collagen health
- Maintain/support energy levels
- Maintain/support energy production
- Relieve weariness/tiredness/fatigue/feeling of weakness when dietary intake is inadequate
- Maintain/support healthy growth and development in children
- Maintain/support healthy growth and development
- Maintain/support general health and wellbeing
- Maintain/support connective tissue health
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Maintain/support cardiovascular system health
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support muscle health
- Maintain/support healthy neuromuscular system/function
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Maintain/support (state vitamin/mineral/nutrient) levels in the body when dietary intake is inadequate
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when dietary intake is inadequate in adults
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in children over 12 years of age
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in adults
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when dietary intake is inadequate in children over 12 years of age
- Maintain/support (state vitamin/mineral) within normal range
- Maintain/support nervous system health
- Maintain/support nervous system function



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Maintain/support skin health

**Indication Requirements**

Product presentation must not imply or refer to serious cardiovascular conditions.  
 Product presentation must not imply or refer to serious immunological diseases.  
 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).  
 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 mental illnesses, disorders or conditions.  
 Label statement: If symptoms persist, talk to your health professional.  
 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 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.  
 Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.  
 Product presentation must not imply or refer to chronic fatigue syndrome.

**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.  
 Adults only.  
 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 medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

**Additional Product information**

**Pack Size/Poison information**

**Pack Size** **Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Oral Liquid  
**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Cola acuminata seed Extract liquid</b>	<b>391 mg/mL</b>
Equivalent: Cola acuminata (Dry)	9.1 mg/mL
<b>colecalfiferol</b>	<b>545 ng/mL</b>
<b>d-alpha-tocopheryl acetate</b>	<b>916 microgram/mL</b>
<b>Echinacea pallida root Extract liquid</b>	<b>391 mg/mL</b>
Equivalent: Echinacea pallida (Dry)	1.01 mg/mL
<b>Macrocystis pyrifera whole plant Extract liquid</b>	<b>391 mg/mL</b>
Equivalent: Macrocystis pyrifera (Dry)	2.5 mg/mL
<b>nicotinamide</b>	<b>2.18 mg/mL</b>
<b>pyridoxine hydrochloride</b>	<b>266 microgram/mL</b>
Equivalent: pyridoxine	218 microgram/mL
<b>retinol palmitate</b>	<b>119.9 microgram/mL</b>
Equivalent: vitamin A	65.4 RE
<b>riboflavin sodium phosphate</b>	<b>224 microgram/mL</b>

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Equivalent: riboflavin	164 microgram/mL
<b>Silybum marianum fruit Extract liquid</b>	<b>391 mg/mL</b>
Equivalent: Silybum marianum (Dry)	10.1 mg/mL
<b>thiamine hydrochloride</b>	<b>216 microgram/mL</b>
Equivalent: thiamine	164 microgram/mL
<b>Triticum aestivum fruit Extract liquid</b>	<b>391 mg/mL</b>
Equivalent: Triticum aestivum (Dry)	2.5 mg/mL

**Other Ingredients (Excipients)**

Apricot  
ascorbic acid  
Flavour  
fructose  
Guar Gum  
Guava  
orange  
Passiflora edulis  
purified water  
xanthan gum  
Yeast autolysate

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