



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

## Public Summary

<b>Summary for ARTG Entry:</b>	407956	Nature's Way Extra Strength Zinc 40mg
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Pharmacare Laboratories Pty Ltd	
<b>Postal Address</b>	PO Box 384, MONA VALE, NSW, 1660 Australia	
<b>ARTG Start Date</b>	21/04/2023	
<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 . Nature's Way Extra Strength Zinc 40mg

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	10/05/2023
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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 energy production  
Maintain/support general health and wellbeing  
Maintain/support connective tissue health  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Maintain/support immune system to fight illness  
Maintain/support (state vitamin/mineral/nutrient) levels in the body  
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)  
Maintain/support reproductive system health  
Maintain/support prostate health when dietary intake is inadequate  
Maintain/support sperm production  
Maintain/support testosterone level  
Maintain/support skin health  
Maintain/support skin integrity/structure  
Maintain/support wound healing  
Maintain/support skin repair/healing/regeneration

### Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.  
Product presentation must not imply or refer to infertility.  
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.  
Product presentation must not imply or refer to serious genitourinary conditions like Benign Prostatic Hypertrophy, erectile dysfunction or hormone therapy.  
If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is



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inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

**Additional Product information**

**Pack Size/Poison information**

Pack Size	Poison Schedule
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**Components**

1 . Formulation 1

**Dosage Form**                      Tablet, film coated  
**Route of Administration**        Oral

**Visual Identification**

**Active Ingredients**

<b>betacarotene</b>	<b>4.2 mg</b>
<b>magnesium amino acid chelate</b>	<b>100 mg</b>
Equivalent: magnesium	20 mg
<b>pyridoxine hydrochloride</b>	<b>10.95 mg</b>
Equivalent: pyridoxine	9.01 mg
<b>zinc glycinate</b>	<b>130.6 mg</b>
Equivalent: zinc	40 mg

**Other Ingredients (Excipients)**

- ascorbyl palmitate
- calcium hydrogen phosphate dihydrate
- Carnauba Wax
- colloidal anhydrous silica
- croscarmellose sodium
- crospovidone
- dl-alpha-tocopherol
- hypromellose
- iron oxide yellow
- macrogol 400
- macrogol 8000
- magnesium stearate
- microcrystalline cellulose
- modified food starch
- povidone
- silicon dioxide
- Sunflower Oil

Public Summary

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