



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

## Public Summary

<b>Summary for ARTG Entry:</b>	366250	BergaMet Pro+
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	DOJS Holdings Pty Ltd	
<b>Postal Address</b>	49 Retreat Street, BRIDGEMAN DOWNS, QLD, 4035 Australia	
<b>ARTG Start Date</b>	17/05/2021	
<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 . BergaMet Pro+

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	17/05/2021
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### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Maintain/support natural liver cleansing/detoxification processes  
Anti-inflammatory/relieve inflammation  
Maintain/support healthy blood circulation  
Helps in the maintenance of healthy blood lipids/blood fats  
Helps maintain/support healthy cholesterol  
Helps maintain/support healthy blood sugar/glucose  
Maintain/support cardiovascular system health  
Maintain/support artery health  
Helps enhance/promote healthy liver function  
Hepatoprotectant/protect the liver  
Maintain/support healthy liver function  
Maintain/support liver health  
Maintain/support healthy immune system function  
Decrease/reduce/relieve symptoms of stress

### 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 only refer to detoxification in relation to natural body processes.  
Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.

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

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

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

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 lowering blood lipids, blood fats and triglycerides.

Product presentation must not imply or refer to lowering or raising blood cholesterol levels from outside of the normal healthy range



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Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

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

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>alpha lipoic acid</b>	<b>50 mg</b>
<b>ascorbic acid</b>	<b>25 mg</b>
<b>chromium picolinate</b>	<b>200 microgram</b>
Equivalent: chromium	25 microgram
<b>Citrus aurantium fruit juice Extract dry concentrate</b>	<b>400 mg</b>
Equivalent: Citrus aurantium (Fresh)	40 g
<b>Olea europaea leaf Extract dry concentrate standardised</b>	<b>100 mg</b>
Equivalent: Olea europaea (Dry)	1.2 g
<b>Piper nigrum fruit Extract dry concentrate standardised</b>	<b>5.263 mg</b>
Equivalent: Piper nigrum (Dry)	107.8915 mg
<b>zinc citrate dihydrate</b>	<b>15.56 mg</b>
Equivalent: zinc	5 mg

**Other Ingredients (Excipients)**

- calcium hydrogen phosphate dihydrate
- Carnauba Wax
- colloidal anhydrous silica
- croscarmellose sodium
- crospovidone
- dl-alpha-tocopherol
- ethanol
- hypromellose
- lecithin
- macrogol 4000
- magnesium stearate
- maltodextrin
- microcrystalline cellulose
- phosphatidyl choline
- polysorbate 80
- polyvinyl alcohol

Public Summary



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purified talc

purified water

silicon dioxide

sodium chloride

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