



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	375467	BergaMet Advanced
ARTG entry for	Medicine Listed	
Sponsor	DOJS Holdings Pty Ltd	
Postal Address	49 Retreat Street, BRIDGEMAN DOWNS, QLD, 4035 Australia	
ARTG Start Date	29/09/2021	
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 . BergaMet Advanced

Product Type	Single Medicine Product	Effective Date	29/09/2021
---------------------	-------------------------	-----------------------	------------

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 drugs/alcohol.
Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.
Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.
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 lowering blood lipids, blood fats and triglycerides.
Label statement: If symptoms persist, talk to your health professional.
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 only refer to detoxification in relation to natural body processes.



Australian Government
Department of Health
Therapeutic Goods Administration

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

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

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

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

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

alpha lipoic acid	50 mg
ascorbic acid	50 mg
Citrus aurantium fruit juice Extract dry concentrate	500 mg
Equivalent: Citrus aurantium (Fresh)	50 g
Olea europaea leaf Extract dry concentrate standardised	50 mg
Equivalent: Olea europaea (Dry)	600 mg
zinc citrate dihydrate	15.55 mg
Equivalent: zinc	5 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
crospovidone
hypromellose
macrogol 4000
magnesium stearate
microcrystalline cellulose
polysorbate 80
polyvinyl alcohol
povidone
purified talc