

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	408592	Astra Recharge
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pt	y Ltd
Postal Address	PO Box 3143, K Australia	IRRAWEE, NSW, 2232
ARTG Start Date	8/05/2023	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	3
Conditions		

Conditions

Products

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.

1. Astra Recharge Product Type Effective Date 8/05/2023 Single Medicine Product **Permitted Indications** Antioxidant/Reduce free radicals formed in the body Traditionally used in Chinese medicine to increase/augment/generate/promote/strengthen qi Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Qi Maintain/support energy levels Aids/assists with recovery from illness/convalescence Relieve feelings of general malaise/general debility Relieve weariness/tiredness/fatigue/feeling of weakness Maintain/support immune system health Maintain/support healthy immune system function Enhance/promote body adaptation to stress Support healthy stress response in the body Decrease/reduce/relieve symptoms of stress Maintain/support mental concentration/focus/clarity Maintain/support mental endurance/stamina Maintain/support cognitive function/mental function Decrease/reduce/relieve sleeplessness Enhance/improve/promote/increase sleep quality/deep sleep Traditionally used in Chinese medicine to loosen chest phlegm Traditionally used in Chinese medicine to decrease/reduce excess mucous Traditionally used in Chinese medicine to expectorant/clear respiratory tract mucous Traditionally used in Chinese medicine to decrease/reduce/relieve cough

Indication Requirements

If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect). Label statement: If symptoms persist, talk to your health professional.

Page 1 of 2

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

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 serious immunological diseases.

Product presentation must not imply or refer to chronic fatigue syndrome.

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Standard Indications				
No Standard Indications included on Record				
Specific Indications				
No Specific Indications included on Record				
Warnings				
No Warnings included on Record				
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				
Astragalus membranaceus root Extract dry concentrate	325 mg			
Equivalent: Astragalus membranaceus (Dry)	6.5 g			
Eleutherococcus senticosus root Extract dry concentrate	100 mg			
Equivalent: Eleutherococcus senticosus (Dry)	1.5 g			
Ganoderma lucidum fruiting body Extract dry concentrate	37.5 mg			
Equivalent: Ganoderma lucidum (Dry)	750 mg			
Ocimum tenuiflorum herb top Extract dry concentrate	125 mg			
Equivalent: Ocimum tenuiflorum (Dry)	2.5 g			
Schisandra chinensis fruit Extract dry concentrate	50 mg			
Equivalent: Schisandra chinensis (Dry)	1000 mg			

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Page 2 of 2

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Other Ingredients (Excipients)

colloidal anhydrous silica croscarmellose sodium

microcrystalline cellulose

Carnauba Wax

crospovidone hypromellose macrogol 400 magnesium stearate maltodextrin

povidone

calcium hydrogen phosphate dihydrate

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