

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	371979	THERMAL SWITCH		
ARTG entry for	Medicine Listed			
Sponsor	Switch Nutrition			
Postal Address	PO Box 787, Mai Australia	roochydore, QLD, 4558		
ARTG Start Date	2/08/2021			
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. THERMAL SWITCH Product Type Effective Date 2/08/2021 Single Medicine Product **Permitted Indications** Antioxidant/Reduce free radicals formed in the body Traditionally used in Ayurvedic medicine to ruchya/increases taste perception and digestion Maintain/support energy levels Maintain/support body metabolism/metabolic rate Maintain/support energy production Maintain/support heat/energy production/thermogenesis Maintain/support healthy eye function Maintain/support eve health Maintain/support healthy eyesight/vision Traditionally used in Ayurvedic medicine to maintain/support general health and wellbeing Maintain/support general health and wellbeing Maintain/support hair health Maintain/support nail health/strength/thickness Traditionally used in Ayurvedic medicine to antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling Maintain/support bone health Traditionally used in Ayurvedic medicine to decrease/reduce/relieve mild rheumatic aches and pains Aid/assist healthy red blood cell production Helps maintain/support haemoglobin formation/synthesis Maintain/support healthy thyroid gland function Maintain/support healthy thyroid hormones Maintain/support thyroid gland health Traditionally used in Ayurvedic medicine to decrease/reduce/relieve colic (wind/gas pain) Traditionally used in Ayurvedic medicine to decrease/reduce/relieve flatulence/carminative Traditionally used in Ayurvedic medicine to maintain/support digestive system health Aid/assist/helps glucose/sugar/carbohydrate metabolism Aid/assist/helps protein synthesis in the body Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

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Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

Maintain/support mental concentration/focus/clarity Temporarily

Maintain/support cognitive function/mental function Temporarily

Maintain/support cognitive function/mental function

Maintain/support nerve conduction

Aid/assist/helps synthesis of neurotransmitters

Maintain/support nervous system health

Maintain/support nervous system function

Maintain/support female reproductive system health

Maintain/support preconception health in healthy females

Maintain/support preconception health in healthy males

Maintain/support reproductive system health in males

Maintain/support healthy reproductive hormones

Maintain/support sperm health in healthy males

Maintain/support sperm production in healthy males

Traditionally used in Ayurvedic medicine to decrease/reduce excess mucous

Maintain/support skin health

Maintain/support skin integrity/structure

Maintain/support skin regeneration

Maintain/support wound healing

Indication Requirements

Product presentation must not imply or refer to any thyroid related diseases

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

Product presentation must not imply or refer to hormone imbalances.

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

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 infertility.

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

Product presentation must only refer to mild rheumatic aches/pains.

Label statement: Not to be used in children under 5 years.

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.

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

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. 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 chronic fatigue syndrome.

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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only.

Additional Product information

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Pack Size		Poison Schedule		
omponents				
1 . Formulation 1				
Dosage Form	Capsule, hard			
Route of Administration	Oral			
Visual Identification				
Active Ingredients				
Alpinia galanga rhizome E	xtract dry concentrate		50 mg	
Equivalent: Alpinia galang	a (Dry)		500 mg	
caffeine			31.34 mg	
calcium folinate			88 microgram	
Equivalent: folinic acid			80 microgram	
Camellia sinensis leaf Ext	ract dry concentrate	100 mg		
Equivalent: Camellia siner	nsis (Dry)	2.5 g		
Capsicum annuum fruit Ex	stract dry concentrate		1 mg	
Equivalent: Capsicum ann	uum (Dry)		6 mg	
chromic chloride hexahyd	rate		358.8 microgram	
Equivalent: chromium			70 microgram	
Gymnema sylvestre leaf E	xtract dry concentrate		50 mg	
Equivalent: Gymnema sylv	vestre (Dry)		1 g	
mecobalamin (co-methylc	obalamin)		50 microgram	
Piper nigrum fruit Extract	dry concentrate		2.11 mg	
Equivalent: Piper nigrum (Dry)		43.26 mg	
Plectranthus barbatus roo	t Extract dry concentrate		47.72 mg	
Equivalent: Plectranthus b	arbatus (Dry)		4.2 g	
potassium iodide			65.4 microgram	
Equivalent: iodine			50 microgram	
pyridoxine hydrochloride			6.07 mg	
Equivalent: pyridoxine			5 mg	
zinc citrate dihydrate			12.45 mg	
Equivalent: zinc			4 mg	
Other Ingredients (Excipie	ents)			
calcium hydrogen phosph	ate dihydrate			
colloidal anhydrous silica				
hypromellose				
magnesium stearate				
maltodextrin				

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