



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	312123 Thyro - HPA Forte N
ARTG entry for	Medicine Listed
Sponsor	Bio-Practica Pty Ltd
Postal Address	651 Portrush Road, GLEN OSMOND, SA, 5064 Australia
ARTG Start Date	3/12/2018
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Thyro - HPA Forte N

Product Type	Effective Date
Single Medicine Product	3/12/2018

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support collagen formation
- Enhance/promote/physical endurance/capacity/stamina during the day in adults
- Relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support general health and wellbeing
- Helps maintain/support healthy cholesterol
- Maintain/support healthy thyroid gland function when dietary intake is inadequate in adults
- Maintain/support thyroid gland health
- Aid/assist thyroid hormone production
- Maintain/support healthy liver function
- Maintain/support immune system health
- Traditionally used in Asian medicine to helps enhance/improve/promote/increase muscle performance/endurance/stamina
- Traditionally used in Eastern European herbal medicine to helps enhance/improve/promote/increase muscle performance/endurance/stamina
- Helps enhance/improve/promote/increase muscle performance/endurance/stamina
- Helps enhance/improve/promote/increase physical/exercise performance
- Helps enhance/improve/promote/increase physical/exercise performance
- Aid/assist/helps protein synthesis in the body

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Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress
 Enhance/promote body adaptation to stress Temporarily in adults
 Enhance/promote body adaptation to stress
 Support healthy stress response in the body
 Support healthy stress response in the body
 Helps reduce occurrence of irritability
 Decrease/reduce/relieve symptoms of mild anxiety
 Decrease/reduce mental/cognitive fatigue
 Traditionally used in Eastern European herbal medicine to enhance/improve/promote/increase cognitive performance
 Maintain/support cognitive function/mental function
 Decrease/reduce/relieve sleeplessness
 Enhance/improve/promote skin healing
 Maintain/support wound healing
 Maintain/support skin repair/healing/regeneration

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
 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 mental illnesses, disorders or conditions.
 Product presentation must not imply or refer to any thyroid related diseases.
 Product presentation must not imply or refer to chronic fatigue syndrome.
 Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
 Product presentation must not imply or refer to serious immunological diseases.
 Product presentation must only refer to mild anxiety.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

This product contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

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

ascorbic acid	100 mg
colecalfiferol	.005 mg
d-alpha-tocopheryl acid succinate	43.03 mg
Equivalent: d-alpha-tocopherol	52.07 IU
potassium iodide	200 microgram
Equivalent: iodine	150 microgram
Rhodiola rosea	25 mg
Equivalent: Rhodiola rosea	200 mg
riboflavine sodium phosphate	13.16 mg
Equivalent: riboflavine	10 mg

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selenomethionine	190 microgram
Equivalent: selenium	75 microgram
tyrosine	500 mg
Withania somnifera	150 mg
Equivalent: Withania somnifera	1.5 g
zinc citrate dihydrate	15.58 mg
Equivalent: zinc	5 mg

Other Ingredients (Excipients)

Acacia
calcium hydrogen phosphate dihydrate
Carnauba Wax
chlorophyllin-copper complex
colloidal anhydrous silica
croscarmellose sodium
crospovidone
dl-alpha-tocopherol
hypromellose
macrogol 400
maize starch
medium chain triglycerides
microcrystalline cellulose
povidone
silicon dioxide
stearic acid
sucrose

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