



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	351799	METAGENICS ANDRO NK
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	16/12/2020	
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 . METAGENICS ANDRO NK

Product Type	Single Medicine Product	Effective Date	16/12/2020
--------------	-------------------------	----------------	------------

Permitted Indications

Aids/assists with recovery from illness/convalescence

Traditionally used in Chinese medicine to aids/assists with recovery from illness/convalescence

Traditionally used in Chinese medicine to antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling

Maintain/support immune system health

Maintain/support healthy immune system function

Maintain/support immune system to fight illness

Traditionally used in Chinese medicine to maintain/support immune system to fight illness

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when sun exposure is inadequate

Traditionally used in Chinese medicine to decrease/reduce/relieve the severity of common cold symptoms

Linked indication - Antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling

Linked indication - Clear/expel/dissolve/resolve Phlegm

Linked indication - Decrease/reduce/relieve cough

Traditionally used in Chinese medicine to decrease/reduce/relieve the severity of common cold symptoms

Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of common cold

Linked indication - Antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling

Linked indication - Clear/expel/dissolve/resolve Phlegm

Linked indication - Decrease/reduce/relieve cough

Traditionally used in Chinese medicine to relieve symptoms of sore throat/pharyngitis

Indication Requirements

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 serious immunological diseases.

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

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

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.

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

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.



Australian Government
Department of Health
Therapeutic Goods Administration

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Andrographis may cause allergic reactions in some people. If you have a severe reaction (such as anaphylaxis), stop use and seek immediate medical attention (or words to that effect).

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral 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

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Tablet, film coated
Route of Administration Oral

Visual Identification

Active Ingredients

Andrographis paniculata herb top Extract dry concentrate	394 mg
Equivalent: Andrographis paniculata (Dry)	6.3 g
calcium ascorbate dihydrate	242.08 mg
Equivalent: ascorbic acid	200 mg
Camellia sinensis leaf Extract dry concentrate standardised	152 mg
Equivalent: Camellia sinensis (Dry)	4.56 g
colecalfiferol	.0125 mg
zinc amino acid chelate	37.5 mg
Equivalent: zinc	7.5 mg

Other Ingredients (Excipients)

Acacia
citric acid
croscarmellose sodium
crospovidone
dl-alpha-tocopherol
glycerol
hypromellose
magnesium stearate
maize starch
medium chain triglycerides
microcrystalline cellulose
silicon dioxide
sucrose
tartaric acid

Public Summary

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.