Public Summary

Summary for ARTG Entry:	326124 Potassium Plus
ARTG entry for	Medicine Listed
Sponsor	Interclinical Laboratories Pty Ltd
Postal Address	PO Box 6474, ALEXANDRIA, NSW, 2015 Australia
ARTG Start Date	11/11/2019
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 . Potassium Plus

Product Type	Single Medicine Product	**Effective Date**	11/11/2019

Permitted Indications

Maintain/support energy levels
Helps convert (state food) into energy
Maintain/support energy production
Maintain/support body electrolyte balance
Helps maintain/support healthy acid/alkali balance in the body
Maintain/support body mucous membrane health
Maintain/support general health and wellbeing
Aid/assist healthy red blood cell production
Helps maintain/support haemoglobin formation/synthesis
Maintain/support cardiovascular system health
Maintain/support healthy cardiovascular system function
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support healthy muscle contraction function
Maintain/support muscle function
Maintain/support healthy neuromuscular system/function
Aid/assist/helps glucose/sugar/carbohydrate metabolism
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

Maintain/support nerve conduction

Maintain/support neuromuscular function

Aid/assist/helps synthesis of neurotransmitters

Maintain/support nervous system health

Maintain/support nervous system function

Maintain/support skin health

Maintain/support kidney function

Indication Requirements

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

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 serious immunological diseases.

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

Product presentation must not imply or refer to kidney disease.

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

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

If product is indicated for supplementation, Label statement: 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.

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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

nicotinamide	**5 mg**
potassium gluconate	**958.08 mg**
Equivalent: potassium	160 mg
pyridoxal 5-phosphate	**2.92 mg**
Equivalent: pyridoxine	2 mg

Other Ingredients (Excipients)

Acacia

Carnauba Wax

colloidal anhydrous silica

glycerol

Guar Gum

lecithin

magnesium stearate

maize starch

microcrystalline cellulose

purified water