Public Summary

Summary for ARTG Entry:	409955 IronUp®
ARTG entry for	Medicine Listed
Sponsor	Pharmametics Products A Division of Max Biocare Pty Ltd
Postal Address	Level 1-2 667 Chapel Street, South Yarra, VIC, 3141 Australia
ARTG Start Date	2/06/2023
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 . IronUp®

Product Type Single Medicine Product **Effective Date** 2/06/2023

Permitted Indications

Maintain/support general health and wellbeing
Maintain/support healthy blood circulation
Aid/assist healthy red blood cell production
Maintain/support blood health
Aid/assist/helps in the maintenance of blood levels of oxygen
Helps maintain/support haemoglobin formation/synthesis
Helps enhance/promote/increase absorption of dietary (state vitamin/mineral/nutrient)
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Maintain/support (state vitamin/mineral) within normal range
Helps maintains/support healthy foetal CNS/brain development
Maintains/support healthy foetal development
Maintain/support healthy pregnancy
Maintain/support maternal health
Help to prevent neural tube defects such as spina bifida and/or anencephaly
Maintain/support preconception health
Maintain/support placenta health/growth
Helps prepare the body for pregnancy

Indication Requirements

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

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

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

Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner.

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 heart disease.

Product presentation must not imply or refer to infertility.

Indication can only be used for medicines that contain folic acid as an active ingredient and the recommended daily dose of the medicine provides a minimum of 400 micrograms of folic acid. Product presentation referring to the prevention of neural tube defects must include at least one of the following label statements: when trying to conceive and during the first trimester of pregnancy, and/or when taken at least four weeks before conception and during the first trimester of pregnancy.

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).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Not for the treatment of iron deficiency conditions (or words to that effect).

Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.

Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida, seek specific medical advice (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	

Active Ingredients

ascorbic acid	**50 mg**
calcium folinate	**130 microgram**
Equivalent: folinic acid	100 microgram
cyanocobalamin	**.01 mg**
folic acid	**400 microgram**
iron (II) glycinate	**88.8 mg**
Equivalent: iron	24 mg
pyridoxine hydrochloride	**6.08 mg**
Equivalent: pyridoxine	5 mg
riboflavine	**5 mg**
thiamine nitrate	**5 mg**

Other Ingredients (Excipients)

citric acid
Gelatin
glycerol
glyceryl monostearate
hydrogenated vegetable oil
iron oxide black
iron oxide red
lecithin
maltodextrin
mannitol
purified water
silicon dioxide

Soya Oil

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