



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	321714	Spatone Liquid Iron - Apple
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Martin & Pleasance Pty Ltd	
<b>Postal Address</b>	PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia	
<b>ARTG Start Date</b>	13/08/2019	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . Spatone Liquid Iron - Apple

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	13/08/2019
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### Permitted Indications

Maintain/support energy levels  
Maintain/support vitality  
Helps enhance/promote general health and wellbeing  
Maintain/support red blood cell health  
Aid/assist/helps in the maintenance of blood levels of oxygen  
Helps maintain/support transport of oxygen in the body  
Aid/assist/helps oxygen transport to body tissues  
Helps maintain/support haemoglobin formation/synthesis  
Maintain/support healthy immune system function  
Enhance/improve/promote/increase (state vitamin/mineral/nutrient) levels in the body  
Maintain/support (state vitamin/mineral/nutrient) levels in the body  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Maintain/support healthy pregnancy

### Indication Requirements

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.

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

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must not imply or refer to heart disease.



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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.

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

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

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

(If the medicine contains one sorbate) Contains [insert name of sorbate] OR (if medicine contains two or more sorbates) Contains sorbates [or words to that effect].

**Additional Product information**

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Sachet	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

**Pack Size/Poison information**

Pack Size	Poison Schedule

**Components**

**1 . Formulation 1**

**Dosage Form** Oral Liquid

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

trefriw wells mineral water	<b>871 microlitre/mL</b>
Equivalent: iron	244 microgram/mL

**Other Ingredients (Excipients)**

- ascorbic acid
- Malus domestica
- potassium sorbate

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