Public Summary

Summary for ARTG Entry:	326278 Superior Soda
ARTG entry for	Medicine Listed
Sponsor	Safe Soda
Postal Address	28 High Road, Burpengary East, QLD, 4505 Australia
ARTG Start Date	15/11/2019
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.

Preparations that contain, as their therapeutically active ingredient, sodium bicarbonate for oral rehydration therapy, are subject to the following conditions: (i) the formulation complies with the requirements specified in the British Pharmacopoeia monograph for Oral Rehydration Salts; (ii) the sodium, potassium and glucose content, and total osmolarity of the solution after it has been prepared according to the instructions on the packet are consistent with the criteria specified by the World Health Organisation (WHO) and the United Nations Childrens Fund (UNICEF) in the document, Expert consultation on oral rehydration salts formulation, 18 July 2001.

Products

1 . Superior Soda

Product Type Single Medicine Product **Effective Date** 11/02/2020

Permitted Indications

Maintain/support body electrolyte balance
Helps restore body electrolyte balance
Helps maintain/support healthy acid/alkali balance in the body
Maintain/support general health and wellbeing
Decrease/reduce/relieve symptoms of occasional episodes of gout
Antacid/reduces stomach acid
Antacid/reduces stomach acid
Decrease/reduce/relieve symptoms of heartburn
Decrease/reduce/relieve muscle cramps
Reduce/decrease mild muscle inflammation
Decrease/reduce/relieve muscle pain/ache/soreness
Decrease/reduce/relieve muscle tension/stiffness
Helps enhance/improve/promote/increase muscle performance/endurance/stamina
Helps enhance/improve muscle recovery time
Helps reduce occurrence of medically diagnosed cystitis

Helps decrease/reduce/relieve burning sensation/irritation upon urination associated with medically diagnosed cystitis

Helps decrease/reduce/relieve symptoms of medically diagnosed cystitis

Urinary alkaliser

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.

Product presentation must only refer to medically diagnosed cystitis.

Product presentation must not imply or refer to gastro oesophageal reflux disease.

Label statement: If pain or irritation persists for more than 48 hours, consult your doctor. The presence of blood in the urine warrants immediate medical attention (or words to that effect).

Label statement: If symptoms persist, worsen or episodes become more frequent talk to your medical practitioner.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If pain or irritation persists for more than 48 hours, consult your doctor. The presence of blood in the urine warrants immediate medical attention (or words to that effect).

If diarrhoea persists for more than 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3-6 years or 48 hours in adults and children over 6 years, seek medical advice (or words to that effect).

If symptoms persist consult your healthcare practitioner (or words to that effect).

Use only as directed

If diarrhoea persists, seek medical advice

The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Powder
Route of Administration	Oral
Visual Identification	

Active Ingredients

sodium bicarbonate	**1 g/g**

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