



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	386664	IBS Relief +
ARTG entry for	Medicine Listed	
Sponsor	JSHealth Vitamins Pty Ltd	
Postal Address	31 Knox Street, Double Bay, Sydney, NSW, 2028 Australia	
ARTG Start Date	3/04/2022 11:00:00 PM	
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 . IBS Relief +

Product Type	Single Medicine Product	Effective Date	4/04/2022
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Permitted Indications

Traditionally used in Western herbal medicine to decrease/reduce/relieve colic (wind/gas pain)

Decrease/reduce/relieve flatulence/carminative

Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative

Relief of symptoms of medically diagnosed Irritable Bowel Syndrome

Decrease/reduce/relieve abdominal pain/discomfort

Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal pain/discomfort

Decrease/reduce/relieve digestive spasms

Traditionally used in Western herbal medicine to decrease/reduce/relieve digestive spasms

Traditionally used in Western herbal medicine to antiemetic/Decrease/reduce/relieve vomiting

Traditionally used in Western herbal medicine to decrease/reduce/relieve nausea

Indication Requirements

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

Product presentation must only refer to medically diagnosed IBS.

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

Label statement: If symptoms persist or worsen talk to your medical practitioner.

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

Public Summary



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Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

Peppermint Oil 187 mg

Other Ingredients (Excipients)

chlorophyllin-copper complex

ethylcellulose

Gelatin

glycerol

medium chain triglycerides

oleic acid

Olive Oil

purified water

sodium alginate

stearic acid

strong ammonia solution

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