

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 168967 IBEROGAST oral liquid solution bottle

ARTG entry for Medicine Registered

Sponsor Bayer Australia Ltd

Postal Address PO Box 182, Gordon NSW 2072, Gordon, NSW, 2072

Australia

ARTG Start Date 11/02/2010

Product Category Medicine

Status Active

Approval Area Registered Complementary Medicines

Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products

1. IBEROGAST oral liquid solution bottle

Product Type Single Medicine Product Effective Date 4/09/2020

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

For the treatment of gastric and abdominal discomfort associated with functional and motility-conditioned gastrointestinal disturbances such as functional dyspepsia and irritable bowel syndrome.

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Container information

Туре	Material	Life Time	Temperature	Closure	Conditions
Bottle	Glass Type I Coloured	I 24 Months	Store below 25 degrees Celsius	Not recorded	Not recorded

degrees Cer

Pack Size Poison Schedule

20mLNot scheduled. Not considered by committee100mLNot scheduled. Not considered by committee50mLNot scheduled. Not considered by committee

Components

1.

Dosage Form Oral Liquid, solution

Route of Administration Oral

Visual Identification Dark brown liquid, clear to light cloudy.

Active Ingredients

Angelica archangelica root Dry 100 microlitre/mL

Equivalent: Angelica archangelica

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Produced at 25.09.2022 at 12:16:36 AEST



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		33.33 mg/mL
	Equivalent: Angelica archangelica	33.33 mg/mL
	Equivalent: Angelica archangelica	33.33 mg/mL
	Equivalent: Angelica archangelica	33.33 mg/mL
(Carum carvi fruit Extract liquid	100 microlitre/mL
	Equivalent: Carum carvi	33.33 mg/mL
	Equivalent: Carum carvi	33.33 mg/mL
	Equivalent: Carum carvi	33.33 mg/mL
	Equivalent: Carum carvi	33.33 mg/mL
(Chelidonium majus herb Dry	100 microlitre/mL
	Equivalent: Chelidonium majus	33.33 mg/mL
	Equivalent: Chelidonium majus	33.33 mg/mL
	Equivalent: Chelidonium majus	33.33 mg/mL
	Equivalent: Chelidonium majus	33.33 mg/mL
(Glycyrrhiza glabra root Extract dry	100 microlitre/mL
	Equivalent: Glycyrrhiza glabra	33.33 mg/mL
	Equivalent: Glycyrrhiza glabra	33.33 mg/mL
	Equivalent: Glycyrrhiza glabra	33.33 mg/mL
	Equivalent: Glycyrrhiza glabra	33.33 mg/mL
ı	beris amara whole plant Extract liquid	150 microgram/mL
	Equivalent: Iberis amara	75 mg/mL
	Equivalent: Iberis amara	75 mg/mL
	Equivalent: Iberis amara	75 mg/mL
	Equivalent: Iberis amara	75 mg/mL
ı	Matricaria chamomilla flower Extract dry	200 microlitre/mL
	Equivalent: Matricaria chamomilla	66.67 mg/mL
	Equivalent: Matricaria recutita	66.67 mg/mL
	Equivalent: Matricaria chamomilla	66.67 mg/mL
	Equivalent: Matricaria chamomilla	66.67 mg/mL
ı	Melissa officinalis leaf Extract liquid	100 microlitre/mL
	Equivalent: Melissa officinalis	33.33 mg/mL
	Equivalent: Melissa officinalis	33.33 mg/mL
	Equivalent: Melissa officinalis	33.33 mg/mL
	Equivalent: Melissa officinalis	33.33 mg/mL
ı	Mentha X piperita leaf Dry	50 microlitre/mL
	Equivalent: Mentha X piperita	16.67 mg/mL
	Equivalent: Mentha X piperita	16.67 mg/mL
	Equivalent: Mentha X piperita	16.67 mg/mL
	Equivalent: Mentha X piperita	16.67 mg/mL
5	Silybum marianum fruit Extract dry	100 microlitre/mL
	Equivalent: Silybum marianum	33.33 mg/mL
	Equivalent: Silybum marianum	33.33 mg/mL
	Equivalent: Silybum marianum	33.33 mg/mL
	Equivalent: Silybum marianum	33.33 mg/mL

Other Ingredients (Excipients)

ethanol

purified water



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