



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	309600	Detox + Debloat
ARTG entry for	Medicine Listed	
Sponsor	JSHealth Vitamins Pty Ltd	
Postal Address	17 Kimberley Street, Vaucluse, NSW, 2030 Australia	
ARTG Start Date	25/09/2018	
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 . Detox + Debloat

Product Type	Single Medicine Product	Effective Date	21/12/2020
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Traditionally used in Western herbal medicine to maintain/support natural body cleansing/detoxification processes
Maintain/support natural body cleansing/detoxification processes
Traditionally used in Western herbal medicine to maintain/support natural liver cleansing/detoxification processes
Anti-inflammatory/relieve inflammation
Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal bloating/distention
Traditionally used in Western herbal medicine to relieve digestive discomfort
Traditionally used in Western herbal medicine to helps enhance/improve/promote/increase bile secretion/flow
Hepatoprotectant/protect the liver
Traditionally used in Western herbal medicine to promote bile flow from liver/chloretic
Maintain/support liver health

Indication Requirements

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
Product presentation must only refer to detoxification in relation to natural body processes.
Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
Product presentation must not imply or refer to gastro oesophageal reflux disease.
Product presentation must not imply or refer to drugs/alcohol.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings



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Do not use if pregnant or likely to become pregnant (or words to that effect)

Do not use while breastfeeding.

Use in children under 12 years is not recommended.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Brassica oleracea var. italica flower Extract dry concentrate	35 mg
Equivalent: Brassica oleracea var. italica (Dry)	350 mg
choline bitartrate	100 mg
Equivalent: choline	41 mg
Curcuma longa rhizome Extract dry concentrate	80 mg
Equivalent: Curcuma longa (Dry)	800 mg
Foeniculum vulgare seed Extract dry concentrate	150 mg
Equivalent: Foeniculum vulgare (Dry)	1.5 g
glutamine	100 mg
glycine	50 mg
inositol	100 mg
Schisandra chinensis fruit Extract dry concentrate	20 mg
Equivalent: Schisandra chinensis (Dry)	500 mg
Silybum marianum fruit Extract dry concentrate	60 mg
Equivalent: Silybum marianum (Dry)	4.2 g
sodium molybdate dihydrate	.126 mg
Equivalent: molybdenum	.05 mg
Taraxacum officinale root Extract dry concentrate	25 mg
Equivalent: Taraxacum officinale (Dry)	500 mg
taurine	150 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
croscarmellose sodium
crospovidone
hypromellose
iron oxide red
macrogol 400
magnesium stearate
microcrystalline cellulose
povidone
pregelatinised maize starch

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