



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	301136	Oestro-BR
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	PO Box 6454, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	21/03/2018	
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 . Oestro-BR

Product Type	Single Medicine Product	Effective Date	3/08/2022
---------------------	-------------------------	-----------------------	-----------

Permitted Indications

Maintain/support natural body cleansing/detoxification processes

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia

Traditionally used in Chinese medicine to maintain/support healthy liver function in/of Liver Qi Stagnation pattern

Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

Traditionally used in Chinese medicine to decrease/reduce/relieve menstrual cycle irregularity/irregular periods

Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of premenstrual tension

Indication Requirements

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

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

Product presentation must only refer to detoxification in relation to natural body processes.

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

Product presentation must not imply or refer to drugs/alcohol.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

Additional Product information

Pack Size/Poison information

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

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 seed Extract dry concentrate	200 mg
Equivalent: Brassica oleracea var. italica (Fresh)	300 mg
Bupleurum falcatum root Extract dry concentrate	100 mg
Equivalent: Bupleurum falcatum (Dry)	1 g
methionine	25 mg
molybdenum trioxide	62.496 microgram
Equivalent: molybdenum	41.66 microgram
Rosmarinus officinalis leaf Extract dry concentrate	200 mg
Equivalent: Rosmarinus officinalis (Dry)	1 g
Vitis vinifera seed Extract dry concentrate standardised	4.4444 mg
Equivalent: Vitis vinifera (Dry)	533.3 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
chlorophyllin-copper complex
colloidal anhydrous silica
croscarmellose sodium
crospovidone
ethylcellulose
hypromellose
macrogol 400
macrogol 8000
magnesium stearate
maltodextrin
microcrystalline cellulose

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary