



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	307546	NuroBalance Forte
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	30/07/2018	
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 . NuroBalance Forte

Product Type	Single Medicine Product	Effective Date	10/08/2021
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Permitted Indications

Traditionally used in Western herbal medicine to relieve weariness/tiredness/fatigue/feeling of weakness

Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety

Maintain/support cognitive function/mental function

Maintain/support nerve conduction

Maintain/support nervous system function

Traditionally used in Persian/Iranian medicine to support healthy emotional/mood balance

Traditionally used in Western herbal medicine to support healthy emotional/mood balance

Support healthy emotional/mood balance

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must only refer to mild anxiety.

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

Product presentation must not imply or refer to chronic fatigue syndrome.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

St John's Wort affects the way many prescription medicines work, including the oral contraceptive pill. Consult your doctor.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule



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Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Albizia julibrissin stem bark outer Extract dry concentrate	75 mg
Equivalent: Albizia julibrissin (Dry)	1.5 g
Crocus sativus stigma Dry	12.6 mg
Equivalent: Crocus sativus (Dry)	42 mg
Eleutherococcus senticosus root Extract dry concentrate standardised	133.33 mg
Equivalent: Eleutherococcus senticosus (Dry)	2 g
Hypericum perforatum herb top flowering Extract dry concentrate standardised	450 mg
Equivalent: Hypericum perforatum (Dry)	2.7 g
inositol	300 mg
zinc amino acid chelate	62.5 mg
Equivalent: zinc	12.5 mg

Other Ingredients (Excipients)

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

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