



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	347095	Femme Forte N
ARTG entry for	Medicine Listed	
Sponsor	Bio-Practica Pty Ltd	
Postal Address	651 Portrush Road, GLEN OSMOND, SA, 5064 Australia	
ARTG Start Date	3/11/2020	
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 . Femme Forte N

Product Type	Single Medicine Product	Effective Date	3/11/2020
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Antioxidant/Reduce free radicals formed in the body
- Traditionally used in Ayurvedic medicine to medhya/brain tonic/improve memory and cognition
- Traditionally used in Chinese medicine to regulate/soothe/smooth/disperse the flow of liver-qi/liver
- Traditionally used in Ayurvedic medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support eye health
- Maintain/support eye health
- Maintain/support healthy growth and development
- Maintain/support general health and wellbeing
- Traditionally used in Ayurvedic medicine to maintain/support general health and wellbeing
- Maintain/support connective tissue health
- Helps enhance/promote red blood cell health
- Helps maintain/support healthy blood sugar/glucose
- Maintain/support healthy cardiovascular system function
- Maintain/support healthy thyroid gland function
- Traditionally used in Chinese medicine to maintain/support gastrointestinal system health
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Traditionally used in Chinese medicine to maintain/support healthy liver function
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Traditionally used in Eastern European herbal medicine to adaptogen/Help body adapt to stress
- Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress
- Traditionally used in Eastern European herbal medicine to aids/assists the body to cope with environmental stress
- Traditionally used in Eastern European herbal medicine to enhance/promote body adaptation to stress
- Traditionally used in Ayurvedic medicine to enhance/promote body adaptation to stress

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Traditionally used in European herbal medicine to decrease/reduce mental/cognitive fatigue
Traditionally used in Western herbal medicine to decrease/reduce mental/cognitive fatigue
Traditionally used in Western herbal medicine to maintain/support mental endurance/stamina
Traditionally used in Ayurvedic medicine to enhance/improve/promote/increase memory/recall
Maintain/support nervous system health
Traditionally used in Ayurvedic medicine to enhance/promote/increase refreshing sleep
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve sleeplessness
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve sleeplessness
Traditionally used in Ayurvedic medicine to maintain/support healthy sleeping patterns
Decrease/reduce/relieve menstrual cycle irregularity/irregular periods
Traditionally used in Western herbal medicine to decrease/reduce/relieve menstrual cycle irregularity/irregular periods
Traditionally used in Western herbal medicine to decrease/reduce/relieve menstrual cycle irregularity/irregular periods
Traditionally used in Chinese medicine to decrease/reduce/relieve menstrual cycle irregularity/irregular periods
Traditionally used in Chinese medicine to decrease/reduce/relieve menstrual spasms/cramps
Traditionally used in Chinese medicine to decrease/reduce/relieve menstruation pain/dysmenorrhoea
Traditionally used in Western herbal medicine to decrease/reduce/relieve breast pain/tenderness associated with premenstrual tension
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of premenstrual tension
Decrease/reduce/relieve symptoms of premenstrual tension
Decrease/reduce/relieve symptoms of premenstrual tension
Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of menstruation
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of menopause
Maintain/support healthy reproductive hormones
Maintain/support skin health
Maintain/support wound healing

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to any thyroid related diseases.
Product presentation must not imply or refer to gastro oesophageal reflux disease.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must not imply or refer to chronic fatigue syndrome.
Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.
Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.
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).
Product presentation must not imply or refer to serious cardiovascular conditions.
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).
Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.
Product presentation must not imply or refer to hormone imbalances.
Product presentation must not imply or refer to serious immunological diseases.
If Ayurvedic terminology is used on medicine label, label statement: Talk to a Ayurvedic practitioner/health professional if you are unsure if this medicine is right for you.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.
Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

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Vitex agnus-castus may affect hormones and medicines such as oral contraceptives. Consult your health professional before use' (or words to that effect).
If symptoms persist consult your healthcare practitioner (or words to that effect).

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

Bupleurum falcatum root Extract dry concentrate	150 mg
Equivalent: Bupleurum falcatum (Dry)	1.5 g
mixed (low-alpha type) tocopherols concentrate	75 mg
potassium iodide	194.9 microgram
Equivalent: iodine	149 microgram
pyridoxal 5-phosphate monohydrate	23.5 mg
Equivalent: pyridoxine	15 mg
Rhodiola rosea root Extract dry concentrate standardised	75 mg
Equivalent: Rhodiola rosea (Dry)	600 mg
selenomethionine	187.5 microgram
Equivalent: selenium	75 microgram
Vitex agnus-castus fruit Extract dry concentrate standardised	100 mg
Equivalent: Vitex agnus-castus (Dry)	1 g
Withania somnifera root Extract dry concentrate standardised	208.33 mg
Equivalent: Withania somnifera (Dry)	2.5 g
zinc citrate dihydrate	46.58 mg
Equivalent: zinc	15 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
crospovidone
hypromellose
macrogol 400
maltodextrin
microcrystalline cellulose
povidone
stearic acid

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