



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	314435	ProgestaLift Capsules
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	19/02/2019	
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 . ProgestaLift Capsules

Product Type	Single Medicine Product	Effective Date	21/10/2020
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Permitted Indications

- Maintain/support natural liver cleansing/detoxification processes
- Maintain/support energy production
- Maintain/support general health and wellbeing
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Maintain/support blood health
- Helps maintain/support haemoglobin formation/synthesis
- Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
- Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal bloating/distention
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Traditionally used in Western herbal medicine to relieve digestive discomfort
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support immune system to fight illness
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Support healthy stress response in the body
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of stress
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support nervous system health
- Traditionally used in Western herbal medicine to calmative/nervous system relaxant
- Traditionally used in Western herbal medicine to nerve/support nervous system
- Maintain/support nervous system function
- Traditionally used in Western herbal medicine to support healthy emotional/mood balance
- Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness

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Traditionally used in Western herbal medicine to maintain/support healthy sleeping patterns
 Traditionally used in Western herbal medicine to maintain/support female reproductive system health
 Traditionally used in Western herbal medicine to decrease/reduce/relieve menstrual cycle irregularity/irregular periods
 Traditionally used in Western herbal medicine to maintain/support/regulate healthy menstrual cycle
 Decrease/reduce/relieve mood changes/mood swings associated with premenstrual tension
 Traditionally used in Western herbal medicine to decrease/reduce/relieve mood changes/mood swings associated with premenstrual tension
 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
 Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of menopause
 Traditionally used in Western herbal medicine to galactagogue/lactagogue/Enhance/improve/promote/increase breast milk production
 Traditionally used in Western herbal medicine to maintain/support healthy reproductive hormones
 Traditionally used in Western herbal medicine to relieve symptoms of acne
 Maintain/support skin health
 Maintain/support skin integrity/structure
 Maintain/support skin repair/healing/regeneration in healthy individuals

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 Label statement: If symptoms persist, talk to your health professional.
 If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
 Product presentation must not imply or refer to hormone imbalances.
 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 serious immunological diseases.
 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 drugs/alcohol.
 Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
 Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner.
 Product presentation must only refer to mild anxiety.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.
 Vitex agnus-castus may affect hormones and medicines such as oral contraceptives. Consult your health professional before use' (or words to that effect).
 Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.
 If symptoms persist consult your healthcare practitioner (or words to that effect).
 WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.
 If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

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Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

calcium pantothenate	55 mg
Equivalent: pantothenic acid	50.61 mg
Melissa officinalis leaf Extract dry concentrate	120 mg
Equivalent: Melissa officinalis (Dry)	1.2 g
nicotinamide	50 mg
Perilla frutescens leaf Extract dry concentrate	16.67 mg
Equivalent: Perilla frutescens (Dry)	200 mg
Petroselinum crispum leaf Extract dry concentrate	10 mg
Equivalent: Petroselinum crispum (Dry)	100 mg
pyridoxal 5-phosphate monohydrate	50 mg
Equivalent: pyridoxine	31.9 mg
quercetin	125 mg
retinol palmitate	1.3744 mg
riboflavin sodium phosphate	25 mg
Equivalent: riboflavin	19 mg
Vitex agnus-castus fruit Extract dry concentrate	100 mg
Equivalent: Vitex agnus-castus (Dry)	1000 mg

Other Ingredients (Excipients)

Acacia

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

disodium edetate

dl-alpha-tocopherol

gellan gum

hypromellose

leucine

maize starch

potable water

potassium acetate

sucrose

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