



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	360002	OestroSense
ARTG entry for	Medicine Listed	
Sponsor	Factors Group Australia Pty Ltd	
Postal Address	Unit B 10-16 South Street, Rydalmere, NSW, 2116 Australia	
ARTG Start Date	7/04/2021	
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 . OestroSense

Product Type	Single Medicine Product	Effective Date	7/04/2021
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support natural liver cleansing/detoxification processes
- Maintain/support general health and wellbeing
- Anti-inflammatory/relieve inflammation
- Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
- Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal feeling of fullness
- Traditionally used in Western herbal medicine to relieve digestive discomfort
- Helps decrease/reduce/relieve mild gastrointestinal tract inflammation
- Traditionally used in Western herbal medicine to decrease/reduce food stagnation associated with poor or sluggish digestion
- Traditionally used in Western herbal medicine to helps enhance/promote healthy liver function
- Traditionally used in Western herbal medicine to hepatoprotectant/protect the liver
- Traditionally used in Western herbal medicine to maintain/support healthy liver function
- Maintain/support healthy liver function
- Maintain/support liver health
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support female healthy hormonal balance
- Maintain/support female reproductive system health
- Maintain/support healthy reproductive hormones

Indication Requirements

- Product presentation must not imply or refer to hormone imbalances.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to serious immunological diseases.
- Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
- 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.

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Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Brassica oleracea var. italica seed Extract dry concentrate	24.9164 mg
Equivalent: Brassica oleracea var. italica (Dry)	383.33 mg
Camellia sinensis leaf Extract dry concentrate	100 mg
Equivalent: Camellia sinensis (Dry)	3 g
Curcuma longa root Extract dry concentrate standardised	33.333 mg
Equivalent: Curcuma longa (Dry)	1.667 g
lycopene	5 mg
Rosmarinus officinalis leaf Extract dry concentrate	33.333 mg
Equivalent: Rosmarinus officinalis (Dry)	233.331 mg
Silybum marianum seed Extract dry concentrate standardised	80 mg
Equivalent: Silybum marianum (Dry)	2.4 g
zinc citrate dihydrate	20.878 mg
Equivalent: zinc	6.67 mg

Other Ingredients (Excipients)

- Acacia
- ascorbyl palmitate
- calcium hydrogen phosphate dihydrate
- calcium saccharate
- colloidal anhydrous silica
- croscarmellose sodium
- hydrolysed maize starch
- hypromellose
- magnesium stearate
- maltodextrin
- maltose
- mixed (high-alpha type) tocopherols concentrate
- Oryza sativa
- potable water
- silicon dioxide
- stearic acid

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