



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	336839	Livatone Plus capsules
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Health Direction Pty Ltd	
<b>Postal Address</b>	PO Box 689, CAMDEN, NSW, 2570 Australia	
<b>ARTG Start Date</b>	22/05/2020	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Livatone Plus capsules

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	22/01/2021
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### Permitted Indications

Traditionally used in European herbal medicine to maintain/support natural liver cleansing/detoxification processes

Traditionally used in European herbal medicine to decrease/reduce/relieve abdominal bloating/distention

Traditionally used in European herbal medicine to helps enhance/promote healthy gallbladder function

Traditionally used in European herbal medicine to helps enhance/improve/promote/increase bile secretion/flow

Traditionally used in European herbal medicine to helps enhance/promote healthy liver function

Hepatoprotectant/protect the liver

Traditionally used in European herbal medicine to maintain/support healthy liver regeneration

Traditionally used in European herbal medicine to decrease/reduce/relieve symptoms associated with occasional overindulgence

### 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 not encourage excessive or harmful consumption of alcohol or other toxic substances.

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 disease in any body organ.

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.

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record



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### Warnings

Not recommended for use by pregnant and lactating women (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.

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.

Keep out of reach of children (or words to that effect).

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

### Additional Product information

### Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Multiple containers	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

### Pack Size/Poison information

Pack Size	Poison Schedule
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### Components

#### 1 . Formulation 1

<b>Dosage Form</b>	Capsule, hard
<b>Route of Administration</b>	Oral

#### Visual Identification

#### Active Ingredients

<b>calcium ascorbate dihydrate</b>	<b>30.26 mg</b>
Equivalent: ascorbic acid	25 mg
<b>calcium folinate</b>	<b>138.89 microgram</b>
Equivalent: folic acid	100 microgram
<b>calcium pantothenate</b>	<b>5 mg</b>
Equivalent: pantothenic acid	4.58 mg
<b>Curcuma longa rhizome Extract dry concentrate</b>	<b>18.75 mg</b>
Equivalent: Curcuma longa (Dry)	375 mg
<b>cyanocobalamin</b>	<b>.025 mg</b>
<b>d-alpha-tocopheryl acid succinate</b>	<b>20.66 mg</b>
<b>nicotinic acid</b>	<b>5 mg</b>
<b>pyridoxine hydrochloride</b>	<b>2.5 mg</b>
Equivalent: pyridoxine	2.06 mg
<b>riboflavin</b>	<b>2.5 mg</b>
<b>selenomethionine</b>	<b>93.2 microgram</b>
Equivalent: selenium	37.5 microgram
<b>Silybum marianum fruit Extract dry concentrate</b>	<b>131.25 mg</b>
Equivalent: Silybum marianum (Dry)	9.1875 g
<b>taurine</b>	<b>150 mg</b>
<b>thiamine hydrochloride</b>	<b>2.5 mg</b>

#### Other Ingredients (Excipients)

calcium hydrogen phosphate  
colloidal anhydrous silica  
hypromellose  
magnesium stearate  
mannitol  
microcrystalline cellulose



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