



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|--------------------------|
| Summary for ARTG Entry: | 393592 | My Liposomal Glutathione |
| ARTG entry for | Medicine Listed | |
| Sponsor | Thera Health Pty Ltd | |
| Postal Address | 18/93 Rivergate Place, Murarrie, QLD, 4172 Australia | |
| ARTG Start Date | 8/08/2022 | |
| 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 . My Liposomal Glutathione

| | | | |
|---------------------|-------------------------|-----------------------|-----------|
| Product Type | Single Medicine Product | Effective Date | 8/08/2022 |
|---------------------|-------------------------|-----------------------|-----------|

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Anti-inflammatory/relieve inflammation
Maintain/support healthy liver function
Maintain/support healthy immune system function

Indication Requirements

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Not recommended for use by pregnant and lactating women (or words to that effect).
Contains ethanol or contains alcohol.
Adults only.

Additional Product information

Pack Size/Poison information

| | |
|------------------|------------------------|
| Pack Size | Poison Schedule |
|------------------|------------------------|

Components

1 . Formulation 1

| | |
|--------------------|-------------|
| Dosage Form | Oral Liquid |
|--------------------|-------------|



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Route of Administration Oral

Visual Identification

Active Ingredients

glutathione 100 mg/mL

Other Ingredients (Excipients)

ethanol
glycerol
lecithin
Lemon Oil
Peppermint Oil
potassium hydroxide
purified water
tocofersolan

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