



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

| | | |
|--------------------------------|-------------------------------------------------|----------------------------------------------|
| Summary for ARTG Entry: | 93906 | SHEEP PLACENTA EXTRACT capsule - hard bottle |
| ARTG entry for | Medicine Listed (Export Only) | |
| Sponsor | Harmex Pty Limited | |
| Postal Address | PO Box 144, STRATHFIELD, NSW, 2135 Australia | |
| ARTG Start Date | 8/04/2003 | |
| Product Category | Medicine | |
| Status | Active | |
| Approval Area | Export only Medicines | |

Conditions

Except where the sponsor has been contracted by an overseas party to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The sponsor shall hold stability data to support the claimed shelf life of the listed medicine according to the labelled storage conditions except where: (i) each overseas importer accepts responsibility for holding stability data for this product; (ii) the sponsor has a written agreement to this effect from each overseas importer; and (iii) the sponsor retains copies of all such agreements while the medicine remains listed on the ARTG.

This product must not be supplied for sale in Australia, including supply via duty free outlets.

Products

1 . SHEEP PLACENTA EXTRACT capsule - hard bottle

| | | | |
|---------------------|-------------------------|-----------------------|-----------|
| Product Type | Single Medicine Product | Effective Date | 8/04/2003 |
|---------------------|-------------------------|-----------------------|-----------|

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

AIDS OR ASSISTS IN MAINTENANCE OR IMPROVEMENT OF GENERAL WELL-BEING.

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

| | |
|------------------|--------------------------------------------|
| Pack Size | Poison Schedule |
| Not Required | Not scheduled. Not considered by committee |

Components

1 . CAPSULE

| | |
|--------------------------------|---------------|
| Dosage Form | Capsule, hard |
| Route of Administration | Oral |

Visual Identification

Active Ingredients

| | |
|-------------------|---------------|
| Sheep | 250 mg |
| Equivalent: Sheep | 2.5 g |

Other Ingredients (Excipients)

ascorbic acid

Public Summary



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Carob gum
Gelatin
magnesium stearate
purified water

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