



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	95335	ProFeme 10
ARTG entry for	Medicine Listed (Export Only)	
Sponsor	Buckley M J T/A Lawley Pharmaceuticals	
Postal Address	PO Box 1146, WEST LEEDERVILLE, WA, 6901 Australia	
ARTG Start Date	2/07/2003	
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. ProFeme 10

Product Type	Single Medicine Product	Effective date	25/10/2011
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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

Progesterone deficiency conditions.

Warnings

No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Tube	Not recorded	2 Years	Store below 25 degrees Celsius	Not recorded	Do not Freeze

Pack Size/Poison information

Pack Size

Not Required

Poison Schedule

Not scheduled. Not considered by committee

Components

1.

Dosage Form

Cream

Route of Administration

Topical

Visual Identification

White soft cream

Active Ingredients

progesterone 100 mg/g

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