Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Pfizer Australia Pty Ltd

for approval to supply

HEMABATE carboprost (as trometamol 250 microgram/mL injection ampoule (Cancelled)

ARTG Identifier AUST R 79070

ARTG Start date 14/06/2001

Product type Registered Medicine

Manufacturer Details	Address	Manufacturing Steps
Contract Pharmaceutical Services of Australia Pty Limited	5 Eden Park Drive NORTH RYDE, NSW, 2113 Australia	Secondary packaging
Pfizer (Perth) Pty Ltd	Technology Park 15 Brodie Hall Drive BENTLEY, WA, 6102 Australia	Secondary packaging Release for supply
Pharmacia and Upjohn Company	7000 Portage Road Kalamazoo, MI, 49001 United States Of America	Active material manufacture Manufacture of dosage form Packaging and labelling Release for supply Quality Control
Pharmacia Australia Pty Limited	59 Kirby Street RYDALMERE, NSW, 2116 Australia	Release for supply
Wesley Community Services Ltd	211 Victoria Road DUNDAS, NSW, 2117 Australia	Secondary packaging

ARTG Standard Conditions

The above Medicine Registered has been entered on the Register subject to the following conditions:

- Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.
- Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products Covered by This Entry

1. HEMABATE carboprost (as trometamol 250 microgram/mL injection ampoule (Cancelled)

Container Type	Container Material	Container Condition	Container Closure	Shelf Life Time	Shelf Life Temperature	Shelf Life Conditions
Ampoule	Glass	Not recorded	Not recorded	2 Years	Store at 2 to 8 degrees Celsius	Do not Freeze Refrigerate

Product Specific Conditions

- Changes as described in the letter dated 25 March 2003 from [redacted].
- Conditions specified in the letter of 7 June 2001 from [redacted] advising of approval for registration of the goods.

Product Permitted Indications

No permitted indications have been recorded against this entry.

Product Indication Requirements

No indication requirements have been recorded against this entry.

Product Standard Indications

No standard indications have been recorded against this entry.

Product Specific Indications

· INDICATIONS: Hemabate is indicated for the treatment of postpartum haemorrhage due to uterine atony which has not responded to conventional methods of management.

Warnings

See Product Information and Consumer Medicine Information for this product.

Dosage Form

Injection

Route of Administration

· Intramuscular

Visual Identification

Clear, colourless solution, free of visible particulate matter.

Additional Product information

Product Formulation(s)

Active Ingredients

	Quantity	Units
Carboprost trometamol	332	microgram/mL

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 79070
ARTG Start Date: 14/06/2001

[redacted]