Summary for ARTG Entry: 123610
BYETTA 10 exenatide 10 micrograms/40 microlitres (2.4mL in total) solution for injection multidose cartridge

ARTG entry for
Medicine Registered

Sponsor
AstraZeneca Pty Ltd

Postal Address
PO Box 131, NORTH RYDE, NSW, 1670 Australia

ARTG Start Date
28/06/2007

Product category
Medicine

Status
Active

Approval area
Drug Safety Evaluation Branch

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

1. BYETTA 10 exenatide 10 micrograms/40 microlitres (2.4mL in total) solution for injection multidose cartridge

Permitted Indications
No Indication Requirements included on Record

Indication Requirements
No Standard Indications included on Record

Specific Indications
Exenatide is indicated as adjunctive therapy to improve glycaemic control in patients with type 2 diabetes mellitus who are taking metformin, a sulfonylurea, or a combination of metformin and a sulfonylurea, or a combination of metformin and a basal insulin, but are not achieving adequate glycaemic control.

Warnings
See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type
Cartridge
Material
Glass Type I Clear
Life Time
36 Months
Temperature
Store at 2 to 8 degrees Celsius
Closure
Not recorded
Conditions
Do not Freeze
Protect from Light

Pack Size/Poison information

Pack Size
1 pre-filled pen (2.4 mL)

Poison Schedule
(S4) Prescription Only Medicine

Components
1. Medicine component

Dosage Form
Injection, solution

Route of Administration
Subcutaneous

Visual Identification
Clear, colourless liquid.

Active Ingredients
Exenatide

250 microgram/mL