Public Summary

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 the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"

Except where the sponsor has been contracted by an overseas partry 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 conditions applying to these goods when they are exported from Australia are given below:

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, other than condition No. 8 and condition No. 9.

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, other than condition No.11

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.

The therapeutic goods grouped in this registration/listing as export only goods under the following names are included in the Australian Register of Therapeutic Goods and may not be supplied in Australia. Export Name(s) to be added:

Products

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

Product Type	Single Medicine Product	**Effective Date**	27/09/2022

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

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

Pack Size/Poison information

Pack Size	Poison Schedule
1 pre-filled pen (2.4 mL)	(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**

Other Ingredients (Excipients)

glacial acetic acid
mannitol
metacresol
sodium acetate
water for injections

Public Summary