



Australian Government
Department of Health
Therapeutic Goods Administration

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 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

Product Type	Single Medicine Product	Effective Date	3/07/2020
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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

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)



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glacial acetic acid
mannitol
metacresol
sodium acetate
water for injections

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