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 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 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 30/01/2023

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

<table>
<thead>
<tr>
<th>Type</th>
<th>Material</th>
<th>Life Time</th>
<th>Temperature</th>
<th>Closure</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cartridge</td>
<td>Glass Type I Clear</td>
<td>36 Months</td>
<td>Store at 2 to 8 degrees Celsius</td>
<td>Not recorded</td>
<td>Protect from Light, Do not Freeze</td>
</tr>
</tbody>
</table>
### Pack Size/Poison information

<table>
<thead>
<tr>
<th>Pack Size</th>
<th>Poison Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 pre-filled pen (2.4 mL)</td>
<td>(S4) Prescription Only Medicine</td>
</tr>
</tbody>
</table>

### Components

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>1. Medicine component</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Dosage Form</strong></td>
<td>Injection, solution</td>
</tr>
<tr>
<td><strong>Route of Administration</strong></td>
<td>Subcutaneous</td>
</tr>
<tr>
<td><strong>Visual Identification</strong></td>
<td>Clear, colourless liquid.</td>
</tr>
</tbody>
</table>

### Active Ingredients

- **exenatide** 250 microgram/mL

### Other Ingredients (Excipients)

- glacial acetic acid
- mannitol
- metacresol
- sodium acetate
- water for injections

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