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 3/10/2018

Permitted Indications

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>Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 pre-filled pen (2.4 mL)</td>
<td>Exenatide 250 microgram/mL</td>
</tr>
</tbody>
</table>

Components

1. Medicine component

Dosage Form

Injection, solution

Route of Administration

Subcutaneous

Visual Identification

Clear, colourless liquid.

Active Ingredients

Exenatide 250 microgram/mL

Produced at 01.11.2018 at 10:35:40 AEDT
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