Public Summary

Summary for ARTG Entry: 328580  XULTOPHY insulin degludec 100 units/mL liraglutide 3.6 mg/mL solution for injection pre-filled pen 3 mL

ARTG entry for Medicine Registered
Sponsor Novo Nordisk Pharmaceuticals Pty Ltd
Postal Address PO Box 1958, North Sydney, NSW, 2059 Australia
ARTG Start Date 22/12/2020
Product Category Medicine
Status Active
Approval Area Drug Safety Evaluation Branch

Medicine under additional monitoring

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. XULTOPHY insulin degludec 100 units/mL liraglutide 3.6 mg/mL solution for injection/pre-filled pen 3 mL

Product Type Single Medicine Product
Effective Date 22/12/2020

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
Xultophy is indicated as an adjunct to diet and exercise for the treatment of adults with type 2 diabetes mellitus to improve glycaemic control in combination with metformin, with or without other oral glucose-lowering medicinal products (see Section 5.1 Pharmacodynamic Properties-Clinical trials and Section 4.4 Special Warnings and Precautions for Use for available data on the different combinations).

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

This product is included in the Black Triangle Scheme

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>24 Months</td>
<td>Store at 2 to 8 degrees Celsius</td>
<td>Neither child resistant closure nor restricted flow insert</td>
<td>Refrigerate 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</td>
<td>(S4) Prescription Only Medicine</td>
</tr>
<tr>
<td>3</td>
<td>(S4) Prescription Only Medicine</td>
</tr>
<tr>
<td>5</td>
<td>(S4) Prescription Only Medicine</td>
</tr>
</tbody>
</table>

Components

1. XULTOPHY insulin degludec 100 units/mL liraglutide 3.6 mg/mL solution for injection/pre-filled pen 3 mL

Dosage Form Solution
Route of Administration Subcutaneous

Visual Identification
Clear, colourless solution provided in a 3 mL pre-filled multidose disposable pen.

Active Ingredients
- Insulin degludec 100 U/mL
- Liraglutide 3.6 U/mL

Other Ingredients (Excipients)
- glycerol
- hydrochloric acid
- phenol
- sodium hydroxide
- water for injections
- zinc