Public Summary

Summary for ARTG Entry: 296337
LYMPHOSEEK kit for the preparation of technetium [99m Tc] tilmanocept injection vial

ARTG entry for
Medicine Registered

Sponsor
HL Pharma Pty Ltd

Postal Address
Level 19 644 Chapel Street, South Yarra, VIC, 3141
Australia

ARTG Start Date
21/12/2018

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. LYMPHOSEEK kit for the preparation of technetium [99m Tc] tilmanocept injection vial

Product Type
Single Medicine Product

Effective Date
26/07/2019

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
This medicinal product is for diagnostic use only. Radiolabelled LYMPHOSEEK is indicated for imaging and intraoperative detection of sentinel lymph nodes draining a primary tumour in adult patients with breast cancer, melanoma, or localised squamous cell carcinoma of the oral cavity. External imaging and intraoperative evaluation may be performed using a gamma detection device.

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>Vial</td>
<td>Glass Type I Clear</td>
<td>18 Months</td>
<td>Store below 25 degrees Celsius</td>
<td>Neither child resistant closure nor restricted flow insert</td>
<td>Protect from Light</td>
</tr>
</tbody>
</table>

Pack Size/Poison information

<table>
<thead>
<tr>
<th>Pack Size</th>
<th>Poison Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>exempt from scheduling - Appendix A; prescription medicine</td>
</tr>
<tr>
<td>1</td>
<td>exempt from scheduling - Appendix A; prescription medicine</td>
</tr>
</tbody>
</table>

Components

1. LYMPHOSEEK kit for the preparation of technetium [99m Tc] tilmanocept injection vial

Dosage Form
Injection, powder for

Route of Administration
Intratumour
Intradermal
Subcutaneous

Visual Identification
White to off-white powder
### Active Ingredients

<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>tilmanocept</td>
<td>50 microgram</td>
</tr>
</tbody>
</table>

### Other Ingredients (Excipients)

- glycine
- hydrochloric acid
- sodium ascorbate
- sodium hydroxide
- stannous chloride dihydrate
- trehalose dihydrate