Summary for ARTG Entry: 285718  FASENRA benralizumab 30 mg in 1 mL solution for injection prefilled syringe

ARTG entry for Medicine Registered
Sponsor AstraZeneca Pty Ltd
Postal Address PO Box 131, NORTH RYDE, NSW, 1670 Australia
ARTG Start Date 2/04/2018 11:00:00 PM
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 manufacture 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.

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:

1. FASENRA benralizumab 30 mg in 1 mL solution for injection prefilled syringe

Permitted Indications

Single Medicine Product

Effective date 28/01/2020

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

FASENRA is indicated as add-on therapy in patients aged 12 years and over with severe eosinophilic asthma (blood eosinophil count greater than or equal to 300 cells/microlitre or greater than or equal to 150 cells/microlitre if on oral corticosteroid treatment) (see Section 5.1 Pharmacodynamic properties [Clinical Trials]).

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>Syringe</td>
<td>Glass Type I Clear</td>
<td>3 Years</td>
<td>Store at 2 to 8 degrees Celsius</td>
<td>Neither child resistant closure nor restricted flow insert</td>
<td>Protect from Light Protect from Heat Do not Shake</td>
</tr>
</tbody>
</table>

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The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown.

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<table>
<thead>
<tr>
<th>Pack Size/Poison information</th>
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<tbody>
<tr>
<td><strong>Pack Size</strong></td>
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<tr>
<td>1</td>
</tr>
<tr>
<td><strong>Components</strong></td>
</tr>
<tr>
<td>1. FASENRA benralizumab 30 mg in 1 mL solution for injection prefilled syringe</td>
</tr>
<tr>
<td><strong>Dosage Form</strong></td>
</tr>
<tr>
<td><strong>Route of Administration</strong></td>
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<tr>
<td><strong>Visual Identification</strong></td>
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<tr>
<td><strong>Active Ingredients</strong></td>
</tr>
<tr>
<td>benralizumab</td>
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