Public Summary

Summary for ARTG Entry: 345973 KOSELUGO selumetinib 10 mg capsule bottle

ARTG entry for Medicine Registered
Sponsor AstraZeneca Pty Ltd
Postal Address PO Box 131, NORTH RYDE, NSW, 1670 Australia
ARTG Start Date 2/12/2021
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. KOSELUGO selumetinib 10 mg capsule bottle

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Effective Date</th>
<th>2/12/2021</th>
</tr>
</thead>
</table>

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
KOSELUGO is indicated for the treatment of paediatric patients aged 2 years and above, with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN).

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>Bottle</td>
<td>HDPE</td>
<td>36 Months</td>
<td>Store below 30 degrees Celsius</td>
<td>Child resistant closure</td>
<td>Protect from Moisture Store in Original Container</td>
</tr>
</tbody>
</table>

Pack Size/Poison information

<table>
<thead>
<tr>
<th>Pack Size</th>
<th>Poison Schedule</th>
<th>(S4) Prescription Only Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>60 capsules</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Components

1. KOSELUGO selumetinib 10 mg capsule bottle

<table>
<thead>
<tr>
<th>Dosage Form</th>
<th>Route of Administration</th>
<th>Visual Identification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capsule, hard</td>
<td>Oral</td>
<td>White to off-white, opaque, size 4 hard capsule, banded and marked with SEL 10 in black ink,</td>
</tr>
</tbody>
</table>

Active Ingredients
selumetinib sulfate
Equivalent: selumetinib

Other Ingredients (Excipients)

Carnauba Wax
carrageenan
hypromellose
iron oxide black
potassium chloride
propylene glycol
purified water
Shellac
strong ammonia solution
titanium dioxide
tocofersolan

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