Public Summary

Summary for ARTG Entry: 346890 YONSA MPRED abiraterone acetate 125 mg tablet bottle and methylprednisolone 4 mg tablet bottle composite pack

ARTG entry for Medicine Registered
Sponsor Sun Pharma ANZ Pty Ltd
Postal Address Suite 2 02 Level 2 12 Waterloo Road, Macquarie Park, NSW, 2113 Australia
ARTG Start Date 29/03/2022
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. YONSA MPRED abiraterone acetate 125 mg tablet bottle and methylprednisolone 4 mg tablet bottle composite pack

Product Type Composite Pack Effective Date 10/10/2023

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
YONSA MPRED is indicated for the treatment of patients with: newly diagnosed high-risk metastatic hormone sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT), or; patients with metastatic advanced prostate cancer (castration resistant prostate cancer, mCRPC) who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy (ADT) or; patients with mCRPC who have received prior chemotherapy containing a taxane.

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>Bottle</td>
<td>HDPE</td>
<td>36 Months</td>
<td>Store below 25 degrees Celsius</td>
<td>Neither child resistant closure nor restricted flow insert</td>
<td>Not recorded</td>
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<tr>
<td>Bottle</td>
<td>HDPE</td>
<td>48 Months</td>
<td>Store below 25 degrees Celsius</td>
<td>Child resistant closure</td>
<td>Not recorded</td>
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</tbody>
</table>

Pack Size/Poison information

<table>
<thead>
<tr>
<th>Pack Size</th>
<th>Poison Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>120 abiraterone acetate 125 mg tablets</td>
<td>(S4) Prescription Only Medicine</td>
</tr>
<tr>
<td>60 Methylprednisolone 4 mg tablets</td>
<td>(S4) Prescription Only Medicine</td>
</tr>
<tr>
<td>30 Methylprednisolone 4 mg tablets</td>
<td>(S4) Prescription Only Medicine</td>
</tr>
</tbody>
</table>

Components

1. methylprednisolone 4 mg tablet bottle

Dosage Form Tablet
### Route of Administration
Oral

### Visual Identification
White to almost white, round, flat, bevelled edge, scored tablets.

### Active Ingredients
- methylprednisolone
  
### Other Ingredients (Excipients)
- Gelatin
- lactose monohydrate
- magnesium stearate
- maize starch
- purified talc

### Dosage Form
Tablet

### Route of Administration
Oral

### Visual Identification
White to off-white modified oval shaped tablet debossed with 125 FP

### Active Ingredients
- abiraterone acetate

### Other Ingredients (Excipients)
- butylated hydroxyanisole
- butylated hydroxytoluene
- croscarmellose sodium
- lactose monohydrate
- microcrystalline cellulose
- sodium lauryl sulfate
- sodium stearyl fumarate

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