Summary for ARTG Entry: 355284
OXONAL 5/2.5 oxycodone hydrochloride 5 mg /naloxone hydrochloride 2.5 mg modified release tablet blister pack

ARTG entry for Medicine Registered
Sponsor AU Pharma Pty Ltd
Postal Address PO Box 616, AVALON, NSW, 2107 Australia
ARTG Start Date 18/08/2022
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. OXONAL 5/2.5 oxycodone hydrochloride 5 mg /naloxone hydrochloride 2.5 mg modified release tablet blister pack

Product Type Single Medicine Product
Effective Date 14/06/2023

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
Oxonal 5/2.5 modified release tablet is indicated for the management of severe pain where: - Other treatment options have failed, are contraindicated, not tolerated or are otherwise inappropriate to provide sufficient management of pain, and; - The pain is opioid-responsive; and; - Requires daily, continuous, long term treatment.Oxonal 5/2.5 modified release tablet is not indicated for use in chronic non-cancer pain other than in exceptional circumstances.Oxonal 5/2.5 modified release tablet is not indicated as an as-needed (PRN) analgesia.Oxonal 5/2.5 is not indicated for the treatment of patients with restless legs syndrome.

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>Blister Pack</td>
<td>PA/Al/PVC/Al - polyamide-aluminium foil-polyvinylchloride/aluminium foil</td>
<td>36 Months</td>
<td>Store below 25 degrees Celsius</td>
<td>Not recorded</td>
<td>Not recorded</td>
</tr>
</tbody>
</table>

Pack Size/Poison information

<table>
<thead>
<tr>
<th>Pack Size</th>
<th>Poison Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>28 tablets</td>
<td>(S8) Controlled Drug</td>
</tr>
</tbody>
</table>

Components

1. OXONAL 5/2.5 oxycodone hydrochloride 5 mg /naloxone hydrochloride 2.5 mg modified release tablet blister pack

Dosage Form Tablet, modified release
Route of Administration Oral
A blue, 9.6 x 4.8mm, elliptic, biconvex coated tablet, engraved with 5 on one side.
### Visual Identification

<table>
<thead>
<tr>
<th>Active Ingredients</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>naloxone hydrochloride dihydrate</td>
<td>2.75 mg</td>
</tr>
<tr>
<td>Equivalent: naloxone hydrochloride</td>
<td>2.5 mg</td>
</tr>
<tr>
<td>oxycodone hydrochloride</td>
<td>5 mg</td>
</tr>
</tbody>
</table>

### Other Ingredients (Excipients)
- brilliant blue FCF aluminium lake
- colloidal anhydrous silica
- hypromellose
- macrogol 3350
- magnesium stearate
- microcrystalline cellulose
- polyvinyl acetate
- polyvinyl alcohol
- povidone
- purified talc
- silicon dioxide
- sodium lauryl sulfate
- titanium dioxide

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