Public Summary

Summary for ARTG Entry: 25356 MYDRIACYL tropicamide 0.5% eye drops bottle

ARTG entry for
Medicine Registered

Sponsor
Alcon Laboratories Australia Pty Ltd

Postal Address
PO Box 357, Macquarie Park Business Hub, NSW, 1670 Australia

ARTG Start Date
15/10/1991

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"

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. MYDRIACYL tropicamide 0.5% eye drops bottle

Product Type
Single Medicine Product

Effective Date
4/01/2023

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
INDICATIONS AS AT 14 JULY 2003 : Used to produce mydriasis and cycloplegia for diagnostic purposes.

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>
</table>
| Bottle| LDPE     | 3 Years   | Store below 25 degrees Celsius | Not recorded | Do not Refrigerate  
Protect from Light  
Discard 4 weeks after opening  
Keep Container  
Tightly Closed/Airtight |

Pack Size/Poison information

<table>
<thead>
<tr>
<th>Pack Size</th>
<th>Poison Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>15mL</td>
<td>(S4) Prescription Only Medicine</td>
</tr>
</tbody>
</table>

Components

1. Medicine Component

Dosage Form
Eye Drops, solution

Route of Administration
Ophthalmic

Visual Identification
Clear solution
### Active Ingredients

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
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<tbody>
<tr>
<td>tropicamide</td>
<td>5 mg/mL</td>
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</tbody>
</table>

### Other Ingredients (Excipients)

- benzalkonium chloride
- disodium edetate
- hydrochloric acid
- purified water
- sodium chloride
- sodium hydroxide