



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 263083 LANTIM 50/5 latanoprost 50 microgram/mL and timolol 5 mg/mL (as maleate) eye drops solution bottle

ARTG entry for Medicine Registered
Sponsor Juno Pharmaceuticals Pty Ltd
Postal Address Level 2 6 Bond Street, South Yarra, VIC, 3141
 Australia
ARTG Start Date 20/03/2017
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. LANTIM 50/5 latanoprost 50 microgram/mL and timolol 5 mg/mL (as maleate) eye drops solution bottle

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective date | 20/03/2017 |
|---------------------|-------------------------|-----------------------|------------|

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

Reduction of elevated intraocular pressure in patients with open-angle glaucoma and ocular hypertension who are insufficiently responsive to beta-blockers, prostaglandins or other intraocular pressure lowering medications. Latanoprost/timolol (50 microgram/mL/5 mg/mL) eye drops should not be used to initiate therapy.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

| Type | Material | Life Time | Temperature | Closure | Conditions |
|--------|----------|-----------|---------------------------------|--------------|---|
| Bottle | LDPE | 21 Months | Store at 2 to 8 degrees Celsius | Not recorded | Refrigerate Do not Freeze Protect from Light Discard 4 weeks after opening |

Pack Size/Poison information

| | |
|------------------|---------------------------------|
| Pack Size | Poison Schedule |
| 1 x 2.5 mL | (S4) Prescription Only Medicine |
| 3 x 2.5 mL | (S4) Prescription Only Medicine |

Components

1. LANTIM 50/5 latanoprost 50 microgram/mL and timolol 5 mg/mL (as maleate) eye drops solution bottle

| | |
|--------------------------------|---------------------------|
| Dosage Form | Eye Drops, solution |
| Route of Administration | Ophthalmic |
| Visual Identification | Clear, colourless liquid. |

Active Ingredients

| | |
|--------------------|------------------|
| Latanoprost | .05 mg/mL |
|--------------------|------------------|

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Timolol maleate

6.83 mg/mL

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