



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 185416 GOFEX 200 CLEARCAP ibuprofen 200 mg soft capsule blister pack

ARTG entry for	Medicine Registered
Sponsor	Mega Lifesciences (Australia) Pty Ltd
Postal Address	60 National Avenue, PAKENHAM, VIC, 3810 Australia
ARTG Start Date	16/06/2011
Product Category	Medicine
Status	Active
Approval Area	Non-Prescription Medicines

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 . GOFEX 200 CLEARCAP ibuprofen 200 mg soft capsule blister pack

Product Type	Single Medicine Product	Effective Date	16/06/2011
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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

Temporary relief of: acute pain and discomfort where inflammation is present such as back, neck and muscle pain, muscular aches, pain of strains and sprains, headache, migraine headache, tension headache, period pain, toothache & dental pain, arthritic pain, rheumatic pain, pain of neuralgic conditions, tennis elbow pain, sore throat, sinus pain, and aches & pains associated with the common cold and flu. Reduces fever.

Warnings

No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	PVC/PVDC/Al	18 Months	Store below 25 degrees Celsius	Neither child resistant closure nor restricted flow insert	Keep Container Tightly Closed/Airtight

Pack Size/Poison information

Pack Size	Poison Schedule
70	(S2) Pharmacy Medicine
50	(S2) Pharmacy Medicine
80	(S2) Pharmacy Medicine
20	Not Scheduled after consideration by Committee
30	(S2) Pharmacy Medicine
60	(S2) Pharmacy Medicine
100	(S2) Pharmacy Medicine
90	(S2) Pharmacy Medicine
40	(S2) Pharmacy Medicine
10	Not Scheduled after consideration by Committee

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Components

1.

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	10 minim, green transparent oblong soft gelatin capsule.

Active Ingredients

ibuprofen	200 mg
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Other Ingredients (Excipients)

fast green FCF
Gelatin
macrogol 600
potassium hydroxide
purified water
sorbitol solution (70 per cent) (non-crystallising)

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