Public Summary

Summary for ARTG Entry:	79045 GENIX 7.5MG meloxicam 7.5mg tablet blister pack
ARTG entry for	Medicine Listed (Export Only)
Sponsor	Genesis Pharma Pty Ltd
Postal Address	PO Box 82, RIVERWOOD, NSW, 2210 Australia
ARTG Start Date	12/06/2001
Product Category	Medicine
Status	Active
Approval Area	Export only Medicines

Conditions

Except where the sponsor has been contracted by an overseas partry to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The conditions applying to these goods when they are exported from Australia are given below:

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, other than condition No. 8 and condition No. 9.

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, other than condition No.11

Products

1 . GENIX 7.5MG meloxicam 7.5mg tablet blister pack

Product Type	Single Medicine Product	**Effective Date**	3/07/2002

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

Relief of the signs & symptoms of osteoarthritis.

Warnings

No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	Not recorded	3 Years	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
not applicable	Not scheduled. Not considered by committee

Components

1 . tablet

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	Small round bi-convex yellow clear film coated tablet

Active Ingredients

meloxicam	**7.5 mg**
Other Ingredients (Excipients)	
calcium hydrogen phosphate dihydrate	
Carnauba Wax	
colloidal anhydrous silica	
croscarmellose sodium	
hypromellose	
macrogol 400	
magnesium stearate	
microcrystalline cellulose	
povidone	