Public Summary

Summary for ARTG Entry:	370635 Eagle Clinical PEA Max
ARTG entry for	Medicine Listed
Sponsor	Integria Healthcare Australia Pty Ltd
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia
ARTG Start Date	6/07/2021
Product Category	Medicine
Status	Active
Approval Area	Listed Medicines

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1 . Eagle Clinical PEA Max

Product Type Single Medicine Product **Effective Date** 6/07/2021

Permitted Indications

Analgesic/Anodyne/relieve pain

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

For practitioner dispensing only.

The medicine may interact with other prescription analgesic medicines, please consult your healthcare practitioner before use.

Not to be used for more than 21 consecutive days.

Adults only.

If symptoms persist, seek the advice of a healthcare professional.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

Visual Identification

Active Ingredients

palmidrol	**149.9953 mg**
Other Ingredients (Excipients)	
calcium hydrogen phosphate dihydrate	
colloidal anhydrous silica	
disodium edetate	
dl-alpha-tocopheryl acetate	
gellan gum	
hypromellose	
lecithin	
Lime Oil Coldpressed	
magnesium stearate	
medium chain triglycerides	
microcrystalline cellulose	
Olive Oil	
PEG-35 castor oil	
potable water	
potassium acetate	
silicon dioxide	

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