Public Summary

Summary for ARTG Entry:	91836 PEGASYS peginterferon alfa-2a 135 micrograms/0.5mL injection pre-filled syringe
ARTG entry for	Medicine Registered
Sponsor	Roche Products Pty Ltd
Postal Address	PO Box 255, DEE WHY, NSW, 2099 Australia
ARTG Start Date	28/05/2003
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 . PEGASYS peginterferon alfa-2a 135 micrograms/0.5mL injection pre-filled syringe

Product Type Single Medicine Product **Effective Date** 11/01/2019

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

Chronic Hepatitis C (CHC): The combination of PEGASYS and COPEGUS is indicated for the treatment of chronic heptitis C in patients who have received no prior interferon therapy (treatment naive patients) and patients who have failed previous treatment with interferon alfa (pegylated or non-pegylated) alone or in combination therapy with ribavirin. The combination of PEGASYS and COPEGUS is also indicated for the treatment of chronic hepatitis C in patients with clinically stable human immunodeficiency virus (HIV) co-infection who have previously not received interferon therapy. PEGASYS monotherapy is indicated for the for the treatment of chronic heptitis C in treatment naive patients (see Dosage and Administration; Chronic Hepatitis C: Treatment naive patients). Patients must be 18 years of age or older and have compensated liver disease. Chronic Hepatitis B (CHB): PEGASYS is indicated for the treatment of chronic heptitis B in adult patients with evidence of viral replication and liver inflammation and compensated liver disease.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Syringe	Glass Type I Clear	4 Years	Store at 2 to 8 degrees Celsius	Not recorded	Protect from Light

Pack Size/Poison information

Pack Size	Poison Schedule
4 pre-filled syinges with needles	(S4) Prescription Only Medicine

Components

1 . Medicine Component

Dosage Form	Injection, solution
Route of Administration	Subcutaneous
Visual Identification	Clear, colourless to light yellow solution, practically free from particles.

Active Ingredients

Peginterferon alfa-2a	**135 microgram**
Other Ingredients (Excipients)	
acetic acid	
benzyl alcohol	
polysorbate 80	
sodium acetate	
sodium chloride	
water for injections	

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