

**Australian Government** 

## **Department of Health**

# Therapeutic Goods Administration

## **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 Eva	aluation 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 Indication	Permitted Indications						
No Permitted Indica	No Permitted Indications included on Record						
Indication Require	Indication Requirements						
No Indication Requi	No Indication Requirements included on Record						
Standard Indicatio	Standard Indications						
No Standard Indicat	No Standard Indications included on Record						
Creatific Indications							

### **Specific Indications**

Chronic Hepatitis C (CHC): The combination of PEGASYS and COPEGUS is indicated for the treatment of chronic hepititis 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 treatment of chronic hepatitis 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 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 Mat	iterial	Life Time	Temperature	Closure	Conditions		
••	ass 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 nee	eedles (S4) Prescription Only Medicine						
Components							
1 . Medicine Component							
Dosage Form	Injection, solution	Injection, solution					
Route of Administration	Subcutaneous	Subcutaneous					
Visual Identification	Clear, colourles	Clear, colourless to light yellow solution, practically free from particles.					
Active Ingredients							

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Peginterferon alfa-2a

Other Ingredients (Excipients)

acetic acid benzyl alcohol polysorbate 80 sodium acetate sodium chloride water for injections 135 microgram

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