

Site of administration

Subcutaneous administration of Pegasys should be limited to the abdomen and thigh. Exposure to Pegasys was decreased in studies following administration of Pegasys in the arm compared to administration in the abdomen and thigh.

5.3 PRECLINICAL SAFETY DATA

The preclinical toxicity studies conducted with Pegasys were limited due to species specificity of interferons. Acute and chronic toxicity studies have been carried out in cynomolgus monkeys, and the findings observed in peginterferon alfa-2a dosed animals were similar in nature to those produced by interferon alfa-2a.

Pegasys plus ribavirin

When used in combination with ribavirin, Pegasys did not cause any effects in monkeys not previously seen with either active substance alone. The major treatment-related change was reversible mild to moderate anaemia, the severity of which was greater than that produced by either active substance alone.

Carcinogenicity

Pegasys has not been tested for its carcinogenic potential.

Mutagenicity

Pegasys was neither mutagenic nor clastogenic when tested in the Ames bacterial mutagenicity assay and in the *in vitro* chromosomal aberration assay in human lymphocytes, either in the presence or absence of metabolic activation. Please refer also to the approved ribavirin prescribing information

6. PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Sodium chloride
Benzyl alcohol
Sodium acetate
Acetic acid
Polysorbate 80
Water for injections.

6.2 INCOMPATIBILITIES

It is inappropriate to mix Pegasys with other products.

6.3 SHELF LIFE

48 months

6.4 SPECIAL PRECAUTIONS FOR STORAGE

This medicine should not be used after the expiry date shown on the pack.

Store in the refrigerator at 2 – 8 °C.

Do not freeze or shake.

Store in the original package to protect from light.

6.5 NATURE AND CONTENTS OF CONTAINER

Pegasys 180 mcg prefilled disposable glass syringe Pack of 4

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING

Parenteral products should be inspected visually for particulate matter and discoloration before administration, whenever solution and container permit.

The following points should be strictly adhered to regarding the use and disposal of syringes and other medicinal sharps:

- Needles and syringes should never be reused.
- Place all used needles and syringes into a sharps container (puncture-proof disposable container).
- Keep this container out of the reach of children.
- Placing used sharps containers in the household waste should be avoided.
- Dispose of the full container according to local requirements or as instructed by your healthcare provider.

For home use, a puncture resistant container for the disposal of used syringes and needles should be supplied to the patients.

The release of medicines into the environment should be minimised. Medicines should not be disposed of via wastewater and disposal through household waste should be avoided. Unused or expired medicines should be returned to a pharmacy for disposal.

7. MEDICINE SCHEDULE

Prescription medicine

8. SPONSOR

Pharmacy Retailing (NZ) Ltd
t/a Healthcare Logistics
PO Box 62027 Sylvia Park
Auckland 1644
New Zealand
Telephone: (09) 918 5100

9. DATE OF FIRST APPROVAL

7 February 2003

10. DATE OF REVISION OF THE TEXT

30 May 2022

Summary of Changes Table

Section Changed	Summary of new information
8.0	Change of contact details due to sponsorship change.