

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Pegasys?

Pegasys contains the active ingredient peginterferon alfa-2a. Pegasys is used to treat chronic hepatitis B or C, which are viral infections of the liver.

For more information, see Section [1. Why am I using Pegasys?](#) in the full CMI.

### 2. What should I know before I use Pegasys?

Do not use if you have ever had an allergic reaction to Pegasys or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Pegasys?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Pegasys and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Pegasys?

- Pegasys, is usually administered as a 180 mcg per 0.5 mL injection, alone or with ribavirin.
- Pegasys is administered by subcutaneous injection once a week for 24 to 72 weeks. This means that Pegasys is injected with a short needle into the fatty tissue just under the skin in the stomach or thigh.

More instructions can be found in Section [4. How do I use Pegasys?](#) in the full CMI.

### 5. What should I know while using Pegasys?

<b>Things you should do</b>	Remind any doctor, dentist, pharmacist or nurse you visit that you are using Pegasys. Tell your doctor if you are pregnant or plan to become pregnant, or if you are breastfeeding or plan to breastfeed. If you are about to have any blood tests, tell your doctor that you are using Pegasys, as it may interfere with the results of some tests.
<b>Things you should not do</b>	Do not stop using Pegasys suddenly (if relevant). Do not use Pegasys if you have severe depression or think about committing suicide.
<b>Driving or using machines</b>	Be careful driving or operating machinery until you know how Pegasys affects you.
<b>Drinking alcohol</b>	Tell your doctor if you drink alcohol. If you drink alcohol, dizziness, drowsiness or light-headedness may be worse.
<b>Looking after your medicine</b>	Keep Pegasys in its original pack until it is time to use it. Do not shake. Keep Pegasys in the refrigerator between 2°C to 8°C. Do not freeze. Keep Pegasys away from light.

For more information, see Section [5. What should I know while using Pegasys?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects include fever, muscle/joint pain, injection site reaction, nausea, insomnia, diarrhoea, itchiness/rash, irritability, depression, anxiety, aggressive behaviour and colouring of the tongue. Serious side effects include severe chest pain, feeling depressed/suicidal, persistent cough, trouble breathing, increased tiredness, irregular heartbeat, blurred/ loss of vision, severe stomach pain, unusual bleeding/ bruising and swelling of the face/tongue. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# PEGASYS®

pronounced peg-ah-sis

Active ingredient(s): *peginterferon alfa-2a*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Pegasys. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PEGASYS.**

### Where to find information in this leaflet:

- [1. Why am I using Pegasys?](#)
- [2. What should I know before I use Pegasys?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Pegasys?](#)
- [5. What should I know while using Pegasys?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Pegasys?

Pegasys contains the active ingredient peginterferon alfa-2a. Pegasys belongs to a group of medicines called interferons. Pegasys is a long-acting interferon.

Interferons are proteins that modify the response of the body's immune system to help fight infections and severe diseases.

Pegasys is used to treat chronic hepatitis B or C, which are viral infections of the liver. If these viral infections are not managed, in some people, the liver becomes badly damaged and scarred. This is called cirrhosis. Cirrhosis can cause the liver to stop working. Cirrhosis can also be caused by things other than viral infections such as long-term alcoholism.

It is not known if Pegasys can prevent liver failure or liver cancer that is caused by hepatitis infection.

For chronic hepatitis B, Pegasys is usually used alone.

For chronic hepatitis C, Pegasys is best used in combination with ribavirin tablets.

If you are given Pegasys in combination therapy, you should also read the ribavirin Consumer Medicine Information leaflet before use.

Pegasys is used alone for chronic hepatitis C only if you cannot take ribavirin tablets for any reason.

Pegasys treatment will not prevent a hepatitis B or C infected person from giving another person hepatitis B or C.

## 2. What should I know before I use Pegasys?

### Warnings

#### Do not use Pegasys if:

- you are allergic to peginterferon alfa-2a, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- Some symptoms of an allergic reaction include:
  - hives or skin rash
  - swelling of the face, lips or tongue
  - wheezing or troubled breathing
  - faintness

#### Check with your doctor if you:

- you have autoimmune hepatitis
- you have decompensated cirrhosis (severe liver disease)
- you have severe heart problems or any previous heart conditions
- you are HIV co-infected with cirrhosis (Child-Pugh score of 6 or more)
- current, or a history of, depression (feeling low)
- autoimmune disease (where the body's immune system attacks the body's own cells), such as psoriasis (a skin disease)
- history of injecting drug use or excessive alcohol use
- liver and/ or kidney problems
- blood disorders
- diabetes (high blood sugar)
- problems with the thyroid gland
- vision problems
- if you are under 18 years of age

Delayed growth and development has been reported in children under 18 years of age.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known whether Pegasys is harmful to an unborn baby when used by a pregnant woman. If there is a need to use Pegasys when you are pregnant, your doctor will discuss the risks and benefits to you and the unborn baby.

It is not known whether Pegasys or ribavirin passes into breast milk. Your doctor will advise you.

Do not use Pegasys with ribavirin if:

- you have blood disorders including anaemia (low number of red blood cells), thalassaemia (mediterranean anaemia)
- you are pregnant or your female partner is pregnant (if you are male).

If used in combination with ribavirin, birth defects and/or death of an unborn baby may result. Extreme care must be taken to avoid pregnancy during treatment and for 6 months after completion of treatment. Effective contraception must be used during this time.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with Pegasys and affect how it works.**

- theophylline, a medicine used to treat asthma, bronchitis and emphysema
- Sho-saiko-to, a Chinese herbal medicine, also known as Xiao-Chai-Hu-Tang
- methadone, used to treat opioid dependence
- didanosine, stavudine, or zidovudine, medicines used to treat HIV/AIDS
- telbivudine, a medicine used to treat hepatitis B infection
- azathioprine, a medicine used to suppress the immune system.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Pegasys.**

## 4. How do I use Pegasys?

### How much to use

Pegasys, whether given alone or in combination with ribavirin tablets, is usually administered as a 180 mcg per 0.5 mL injection once a week for 24 to 72 weeks depending on the type of virus you are infected with and any previous treatment you have had.

Follow the instructions provided and use Pegasys until your doctor tells you to stop. Your doctor will tell you how much Pegasys to inject according to your individual needs. If necessary, your dose may be changed by your doctor during therapy according to your response. Your doctor will keep track of your response to Pegasys by asking questions and performing occasional laboratory tests.

Do not exceed or change the dose recommended by your doctor.

### When to inject Pegasys

Pegasys should be used as a single injection once a week.

Pegasys is injected under the skin (subcutaneously). This means that Pegasys is injected with a short needle into the fatty tissue just under the skin in the stomach or thigh.

If you are working, you should inject Pegasys at the beginning of your weekend. This will help to reduce the impact of side effects of Pegasys on your ability to work.

### How to inject Pegasys

You should read these directions from beginning to end before starting so that each step of the procedure becomes familiar. These instructions must be carefully followed. Consult your doctor or nurse if you require further instructions.

#### 1. Preparing to self-inject

Before you begin:

- Wash your hands thoroughly
- Find a clean, comfortable area
- Gather all the medicinal supplies you will need:
  - An alcohol swab
  - One Pegasys pre-filled syringe and unused injection needle
  - Some cotton wool
  - A sharps disposal bin
- Check the expiry date. Do not use Pegasys after the expiry date shown on the pre-filled syringe label
- Check the liquid has no discolouration, cloudiness or particles. The liquid should look clear and colourless to slightly yellow
- Remove the Pegasys pre-filled syringe from the fridge. Leave the syringe out of the fridge for 30 minutes

before use; or gently warm the syringe in the palms of your hands for about 1 minute. Be careful not to shake the medication.

## 2. Preparing the syringe and needle

- Remove the protective cap from the end of the needle
- Remove the rubber cap from the end of the syringe
- Place the needle firmly on the end of the syringe
- If you notice any air bubbles in the syringe, hold the syringe with the needle facing upwards, lightly tap the syringe to bring the air bubbles to the top. You may need to gently push the plunger in slightly to push air out of the syringe
- Check the dose of medication your doctor has prescribed. You may need to gently push the plunger to push out some medication to get to the dose your doctor has prescribed
- If you need to put the syringe (with the needle attached) down, make sure the plastic guard covers the needle and place on a clean flat surface
- The syringe is now ready for use.

## 3. Choosing the injection site

- Choose an injection site in your stomach area or the top of your thigh
- Avoid your navel and waistline
- Change injection sites each time to prevent soreness in one spot
- Never inject into a red or swollen area
- Never inject Pegasys into a vein or muscle.

### Preparing the injection site

- Clean the injection site with an alcohol swab and let the skin dry (10 seconds)
- Remove the protective needle guard from the end of the syringe and hold the syringe with the needle facing upwards
- Grab your skin at the injection site firmly between your thumb and forefinger to elevate your skin.

## 5. Injecting the medication

- Hold the syringe at a 45 degree angle to your skin
- Insert the needle in one quick motion with the bevel (flat edge) facing upwards
- Slowly push the plunger all the way down
- Once all the liquid has left the syringe, pull out the needle at the same angle at which you put it in
- Do not recap the needle
- If you notice slight bleeding gently press over the injection site with some cotton wool

## 6. Cleaning up after your injection

- Place the syringe and needle (as one) into the sharps container immediately after injection

- When the sharps container is full, take it to your clinic for correct disposal
- Never throw used needles and syringes in with your household rubbish
- Never re-use the syringe or needle. The needle and syringe are to be used once only.

Remember: Most people can learn to give themselves a subcutaneous injection, but if you experience difficulty, please do not be afraid to ask for help and advice from your doctor, nurse or pharmacist.

Please note that the needle supplied with the Pegasys pre-filled syringe is for subcutaneous injection.

## If you forget to use Pegasys

Pegasys should be used regularly at the same time once every week. If you miss your dose at the usual time, but

- within 2 days after the scheduled dose, you should inject your recommended dose as soon as you remember. Take your next injection on the following regularly scheduled day.
- 3 to 5 days after your scheduled dose, you should inject your recommended dose as soon as you remember. Take your next doses at 5-day intervals until you return to your regularly scheduled day of the week.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

If you are not sure what to do, ask your doctor, nurse or pharmacist.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

## If you use too much Pegasys

If you think that you have used too much Pegasys, you may need urgent medical attention.

### You should immediately:

phone the Poisons Information Centre  
(by calling 13 11 26 in Australia or 0800 764 766 [0800 POISON] in New Zealand), or

contact your doctor, or  
go to the Accident and Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using Pegasys?

### Things you should do

#### Call your doctor straight away if you:

- If you become pregnant while on treatment with Pegasys, immediately tell your doctor.
- If you have not used Pegasys as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.
- If you are about to have any blood tests, tell your doctor that you are using Pegasys. It may interfere with the results of some tests.
- Keep all your doctor's appointments so that your progress can be checked. Your doctor may do blood tests before you start treatment and from time to time to monitor your progress and prevent unwanted side effects.

Remind any doctor, dentist or pharmacist you visit that you are using Pegasys.

### Things you should not do

- Do not stop using Pegasys or change the dosage, without checking with your doctor.
- Do not give Pegasys to anyone else, even if they appear to have the same condition as you.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Pegasys affects you.**

Pegasys can cause dizziness, drowsiness or light-headedness in some people. If you drink alcohol, dizziness, drowsiness or light-headedness may be worse.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

Alcohol may cause dizziness, drowsiness or light-headedness.

### Looking after your medicine

- Keep your Pegasys in its original carton until it is time to use it. If you take the pre-filled syringes out of the pack, they may not keep well.
- Store Pegasys in the refrigerator between 2°C to 8°C. Do not freeze.
- Do not shake Pegasys. Shaking can destroy Pegasys so that it will not work.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

### When to discard your medicine

**Do not use Pegasys after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

**Do not use Pegasys if the medicine is coloured, cloudy, or contains floating particles.**

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>▪ flu-like symptoms such as fever, tiredness/fatigue, chills, muscle or joint pain and headache (these symptoms can usually be relieved by paracetamol)</li><li>▪ injection site reaction</li><li>▪ nausea (feeling sick)</li><li>▪ insomnia (difficulty sleeping)</li><li>▪ temporary hair loss (reversible after finishing treatment)</li><li>▪ loss of appetite</li><li>▪ weight loss</li><li>▪ diarrhoea</li><li>▪ itchiness or rash</li><li>▪ irritability (getting easily upset)</li><li>▪ depression (feeling low, feeling bad about yourself or feeling hopeless)</li><li>▪ anxiety</li><li>▪ aggressive behaviour</li><li>▪ colouring of the tongue</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

Follow the instructions in the carton on how to take care of your medicine properly.

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>signs of anaemia, such as tiredness, shortness of breath when exercising, headaches, dizziness and looking pale</li><li>severe chest pain</li><li>feeling very depressed or suicidal</li><li>thoughts of causing serious harm to others</li><li>persistent cough</li><li>trouble breathing</li><li>irregular heartbeat</li><li>problems with your eyesight, such as blurred or loss of vision</li><li>severe stomach pain</li><li>unusual bleeding or bruising</li><li>swelling of the face or tongue, hives, skin pain</li><li>a red or purple skin rash that spreads</li><li>blisters, particularly on your mouth nose, or eyes</li><li>fever or chills beginning a few weeks after treatment has started</li><li>signs of pulmonary arterial hypertension, such as difficulty breathing or increased tiredness</li></ul> <p>These are serious side effects. You may need urgent medical attention. Serious side effects are rare.</p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

## What Pegasys contains

<b>Active ingredient (main ingredient)</b>	peginterferon alfa-2a
<b>Other ingredients (inactive ingredients)</b>	Each pre-filled syringe also contains: <ul style="list-style-type: none"><li>sodium chloride</li><li>benzyl alcohol</li><li>sodium acetate</li><li>acetic acid</li><li>polysorbate 80</li><li>water for injections</li></ul>
<b>Potential allergens</b>	None

**Do not take this medicine if you are allergic to any of these ingredients.**

## What Pegasys looks like

Pegasys solution for injection is contained in a disposable glass syringe. The solution is clear and colourless to light yellow.

A stainless steel needle is also supplied with the syringe to allow for subcutaneous injection.

Pegasys pre-filled syringes are available in packs of four, in the following strengths:

- 135 mcg per 0.5 mL solution (AUST R 91836)\*
- 180 mcg per 0.5 mL solution (AUST R 91837)

Not available in New Zealand

## Who distributes Pegasys

**Pegasys pre-filled syringes are distributed in Australia by:**

Echo Therapeutics Pty Limited

ABN 628 298 699

Suite 1, 2 Kochia Lane

Lindfield NSW 2070

AUSTRALIA

Medical enquiries: 1300 848 328

This leaflet was prepared on August 2025.