

## 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 Pelgraz?

Pelgraz contains the active ingredient pegfilgrastim. Pelgraz is used to help fight infection, following chemotherapy.

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

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

Do not use if you have ever had an allergic reaction to pegfilgrastim, filgrastim or any of the ingredients listed at the end of the CMI or any medicines or products that are produced using the bacteria, *E.coli*.

**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 Pelgraz?](#) in the full CMI.

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

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

For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Pelgraz?

Pelgraz is given by injection, into the tissues, just below the skin. This is called a subcutaneous injection.

Your doctor, nurse or pharmacist may suggest that you or your carer be taught how to give a subcutaneous injection. This will allow you to give yourself the injection at home.

**It is important that you get special training from your doctor or nurse before you give yourself the injection.**

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

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

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Watch for any signs or symptoms of infection.</li><li>• Remind any doctor, dentist or pharmacist you visit that you are using Pelgraz.</li><li>• Be sure to keep all your doctor's appointments so your progress can be checked.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not use this medicine to treat any other complaints unless your doctor tells you to.</li><li>• Do not give this medicine to anyone else, even if they have the same condition as you.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how Pelgraz affects you.</li></ul>

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

### 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.

Some of the more common and serious side effects are included in full below in the CMI. Speak to your doctor if you have any of these side effects and they worry you.

A very serious side effect is allergic reactions, the symptoms are:

- rash over a large area of the body, itching or hives
- shortness of breath, wheezing or difficulty breathing
- coughing up blood, bleeding from the lung
- swelling of the face, lips, tongue or other parts of the body
- faintness
- rapid pulse or sweating

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.

# PELGRAZ

Active ingredient: *pegfilgrastim*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Pelgraz. **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 Pelgraz.**

**Where to find information in this leaflet:**

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

### 1. Why am I using Pelgraz?

**Pelgraz contains the active ingredient pegfilgrastim.** Pegfilgrastim belongs to a group of medicines called immunostimulants.

**Pelgraz is used to help fight infection, following chemotherapy.**

Some chemotherapy will reduce the number of neutrophils in your body. Although Pelgraz is not a treatment for cancer, it does help the body to make new neutrophils (which are a type of white blood cell). This will reduce your chance of developing infections that might require antibiotics and/or hospital stays. It may even increase your chance of receiving your chemotherapy on time and at the right dose.

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

#### Warnings

**Do not use Pelgraz if you are allergic:**

- to pegfilgrastim, filgrastim or any of the ingredients listed at the end of this leaflet
- any medicines or products that are produced using the bacteria, *E.coli*

Do not use Pelgraz at the same time as your chemotherapy or radiotherapy.

Do not use Pelgraz within 24 hours after you receive chemotherapy. This is because the chemotherapy medicine may stop Pelgraz from increasing the number of infection-fighting neutrophils.

Do not use Pelgraz if it has been left out of the fridge for more than 15 days.

#### Check with your doctor if you have or have had:

- a medical condition affecting the bone marrow or blood
- a family history of a genetic disorder
- sickle cell disease
- problems with your kidneys, liver, heart or other organs
- previous treatment for cancer
- any infections, cancers or tumours
- allergies to any other medicines, foods, preservatives or dyes

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.

If you become pregnant while taking this medicine, tell your doctor immediately.

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

### 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.

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

### 4. How do I use Pelgraz?

Pelgraz is given by injection, into the tissues, just below the skin. This is called a subcutaneous injection.

Your doctor, nurse or pharmacist may suggest that you or your carer be taught how to give a subcutaneous injection. This will allow you to give yourself the injection at home.

**It is important that you get special training from your doctor or nurse before you give yourself the injection.**

If you are not sure about giving yourself the injection or you have any questions, ask your doctor, nurse or pharmacist for help.

Carefully follow all directions given to you by your doctor, nurse or pharmacist.

They may differ from the information in this leaflet.

If you do not understand the instructions in this leaflet, ask your doctor, pharmacist or nurse for help.

## How much to use

The usual dose is one subcutaneous injection (6 mg/0.6 mL), 24 hours after the end of each chemotherapy cycle.

Your doctor will tell you when to begin your treatment and when to stop.

## How to give yourself the injection

This section contains information on how to give yourself an injection of Pelgraz.

**Before you give yourself the injection, it is important that you get special training from your doctor or nurse and read this important information.**

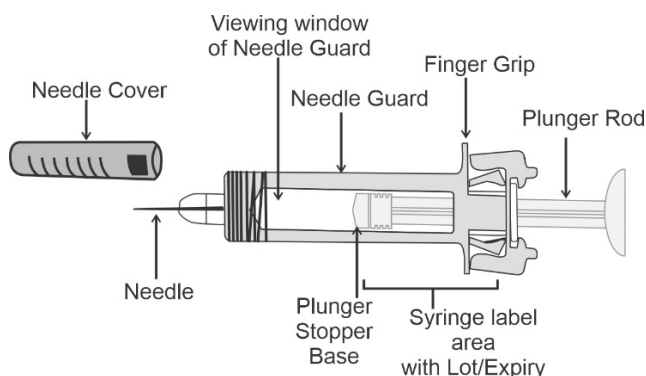
Tell your doctor if you have an allergy to latex. The needle cover on the pre-filled syringe contains a derivative of latex and may cause severe allergic reactions.

DO NOT remove the needle cover from the pre-filled syringe until you are ready to inject.

DO NOT use the pre-filled syringe if it has been dropped on a hard surface. Use a new pre-filled syringe and call your doctor or healthcare provider.

DO NOT attempt to remove the clear pre-filled syringe needle guard from the pre-filled syringe.

### Guide to parts



### Things to do before you inject

**Remove the pre-filled syringe tray from the package and gather the supplies needed for your injection: alcohol wipes, a cotton ball or gauze pad, an adhesive bandage and a sharps disposal container.**

For a more comfortable injection, leave the pre-filled syringe at room temperature for about 30 minutes before injecting.

On a clean, well-lit work surface, place the new pre-filled syringe and the other supplies.

DO NOT try to warm the syringe by using a heat source, such as hot water or microwave.

DO NOT leave the pre-filled syringe exposed to direct sunlight.

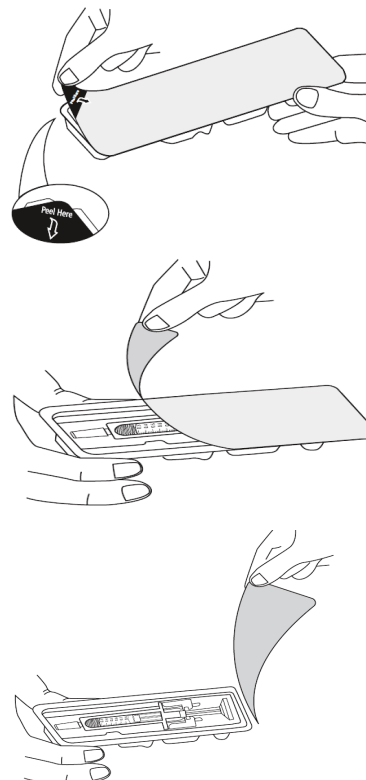
DO NOT shake the pre-filled syringe.

Keep pre-filled syringes out of the sight and reach of children.

### 1. Open the tray, peeling away the cover.

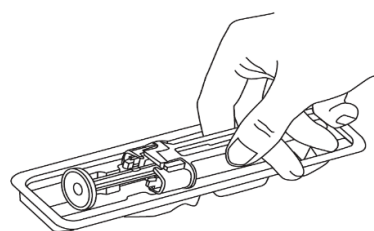
Follow the below instructions for correct handling technique when removing the pre-filled syringe from the packaging, otherwise the needle's safety mechanism may be triggered, making the syringe unusable.

To remove the individual syringe from the blister packaging, start with the corner (as shown by the arrow and "Peel here") and open the blister pack by completely peeling back the top layer



### 2. Hold onto the pre-filled syringe safety guard to remove the pre-filled syringe from the tray.

Remove the syringe from the blister pack by the body as shown below:



### For safety reasons:

DO NOT lift the product by the plunger or needle cover.

DO NOT touch the needle guard activation clips at any time during use. This may trigger the needle's safety mechanism causing the needle to retract (pull back) before your injection is given. This will make the syringe unusable.

### 3. Inspect the medicine and pre-filled syringe. DO NOT use the pre-filled syringe if:

- the medicine is cloudy or there are particles in it. It must be a clear and colourless liquid
- any part appears cracked or broken
- the needle cover is missing or not securely attached
- the expiry date printed on the label has passed the last day of the month shown

In all cases, call your doctor or healthcare provider.

### Selecting and preparing the injection site

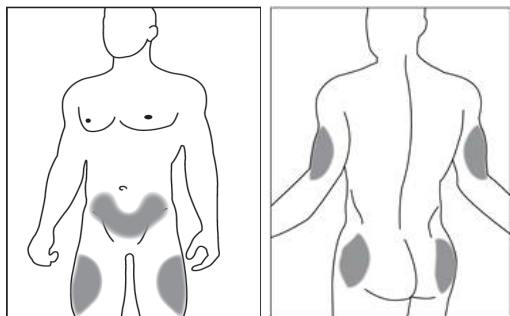
You will need to give yourself an injection into the tissue under the skin, known as a subcutaneous injection:

**Wash hands thoroughly with soap and water.**

**Before you inject this medicine, you must always disinfect the skin on the selected injection site by using an alcohol swab. Let the skin dry.**

Choose an injection site from the most suitable place on your body:

- outer area of your upper arms
- front of your middle thighs
- abdomen, except for the 5 centimetre area around the navel
- upper outer area of your buttocks



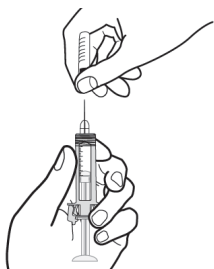
DO NOT touch the selected injection area before injecting.

DO NOT inject into areas where the skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.

From the above options, change the injection site each time you take an injection so that you do not develop soreness in one area.

### Injecting the prescribed dose of medicine

1. Hold the pre-filled syringe by the body (needle guard) with the needle pointing up and away from your body, as this helps to prevent the medicine from accidentally expelling from the syringe.
2. Carefully remove the needle cover straight off, without twisting it.



DO NOT use if the syringe is damaged or the needle is bent.

3. Hold the pre-filled syringe between the thumb and the forefinger of the hand that you will use to inject the medicine.

4. Use the other hand to pinch a fold of the skin at the cleaned injection site between your thumb and forefinger without squeezing it.



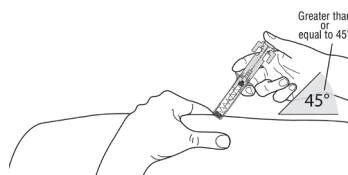
5. Insert the needle into the skin at an angle greater than or equal to 45° (45 degrees), as shown by your nurse, doctor or pharmacist. After the needle is inserted, let go pinching on the fold of skin.



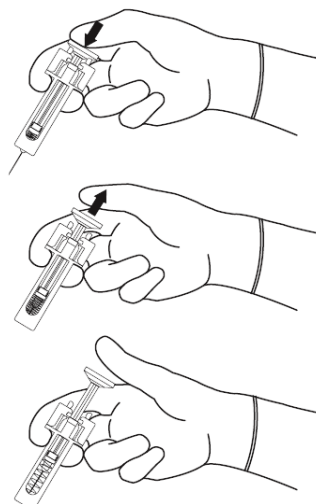
6. Inject the prescribed dose subcutaneously by pushing the plunger with your thumb while grasping the finger grips, as directed by your doctor, nurse or pharmacist.



7. Press the plunger slowly and completely, until all of the medicine has been injected. The needle guard will not be activated unless the entire dose has been administered and you remove downward pressure on the plunger.



8. When the syringe is emptied of all the medicine, slowly lift your thumb from the plunger, which will release the needle guard. The needle will then withdraw from the skin and be covered and locked in place by the needle guard.



9. After the injection, immediately place cotton or gauze on the injected site and apply pressure for several seconds.

### **Disposal**

Place the pre-filled syringe with the needle guard-covered needle into a puncture-proof container for proper disposal. Follow the instructions given by your doctor, nurse or pharmacist on how to properly dispose of containers with used syringes.

Medicines should be disposed of in accordance with local requirements. These measures will help protect the environment.

Always keep the disposal container out of the reach and sight of children.

- DO NOT re-use the pre-filled syringes
- DO NOT recycle pre-filled syringes
- DO NOT throw the pre-filled syringes into household bins

### **Examining the injection site**

If there is blood, press a cotton ball or gauze pad on your injection site. DO NOT rub the injection site. Apply an adhesive bandage if needed.

**If you have any problems, please ask your doctor, nurse or pharmacist for help and advice.**

### **If you forget your injection**

If you miss your scheduled dose, talk to your doctor, nurse or pharmacist as soon as possible.

### **If you use too much Pelgraz**

If you inject more of this medicine than you need, talk to your doctor, nurse or pharmacist. If you feel unwell in any way **you should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the 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 Pelgraz?**

### **Things you should do**

Watch for any signs or symptoms of infection. There are many ways an infection may show itself. Symptoms of an infection include:

- fever (a temperature of 38.2°C or greater, or as your doctor suggests)
- chills
- rash
- sore throat
- diarrhoea
- earache
- difficult or painful breathing, coughing or wheezing

### **Go straight to your hospital if you develop any of these symptoms.**

If you are about to be started on any new medicine, remind your doctor, nurse and pharmacist that you are using this medicine.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your health can be monitored. Your doctor may order blood tests to check the levels of infection-fighting neutrophils and other blood cells, as well as to investigate unwanted side effects.

### **Things you should not do**

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

### **Driving or using machines**

**Be careful driving or operating machinery until you know how Pelgraz affects you.**

### **Looking after your medicine**

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

Keep this medicine in a refrigerator at a temperature of 2°C to 8°C.

This medicine can be removed from the refrigerator and left at room temperature (not above 25°C) for a single period of up to 15 days that ends within the labelled expiry date. Once it has been out at room temperature, it should not be put back into the refrigerator.

You should avoid freezing this medicine; however, if it has been accidentally frozen, allow the medicine to thaw in the refrigerator before use. Do not use this medicine if it has been frozen a second time.

Keep your medicine in the carton. Protect it from light.

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

### **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, nurse or pharmacist if you have any further questions about side effects.

## Common side effects

They are usually mild and short-lived.

Common side effects	What to do
<ul style="list-style-type: none"> <li>temporary bone pain, such as in the lower back or in the long bones of the arms or legs.</li> </ul> <p>This pain is usually relieved with non-prescription painkillers, such as paracetamol. If you continue to have bone pain even after having taken this form of pain relief, you should speak to your doctor, as you may need a prescription medicine.</p> <ul style="list-style-type: none"> <li>headache</li> <li>general aches and pains in joints and muscles</li> <li>reddish or purplish blotches under the skin</li> <li>injection site pain and redness of the skin at the injection site</li> </ul>	<p><b>Speak to your doctor if you have any of these common side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>rash over a large area of the body, itching or hives</li> <li>shortness of breath, wheezing or difficulty breathing</li> <li>coughing up blood, bleeding from the lung</li> <li>swelling of the face, lips, tongue or other parts of the body</li> <li>faintness</li> <li>rapid pulse or sweating</li> <li>swelling or puffiness</li> <li>less frequent urination</li> <li>swelling of your stomach-area (abdomen) and feeling of fullness</li> <li>general feeling of tiredness</li> <li>pain in the upper left side of the stomach (abdomen)</li> <li>left shoulder pain</li> <li>dizziness</li> <li>fever and painful skin lesions most commonly on your arms, legs and sometimes on your face and neck</li> <li>blood in the urine</li> <li>tiredness, shortness of breath, easy bleeding and frequent infections</li> </ul>	<p><b>Stop taking the medicine and call your doctor straight away or go straight to the Emergency Department at your nearest hospital.</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 Pelgraz contains

<b>Active ingredient (main ingredient)</b>	pegfilgrastim
<b>Other ingredients (inactive ingredients)</b>	glacial acetic acid sorbitol polysorbate 20 sodium hydroxide water for injections

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

### What Pelgraz looks like

Pelgraz is a clear, colourless solution supplied as a pre-filled syringe with needle guard (Aust R 308177).

### Who distributes Pelgraz

Accord Healthcare Pty Ltd  
Level 24, 570 Bourke Street  
Melbourne, VIC, 3000  
Australia

This leaflet was prepared in June 2021.