READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

[Pr]LAPELGA®(pronounced) La-pel'-gah
pegfilgrastim Injection

Read this carefully before you start taking **Lapelga®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Lapelga®**.

Lapelga® is a biosimilar biologic drug (biosimilar) to the reference biologic drug Neulasta. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

Serious Warnings and Precautions

- Your spleen may become enlarged and can rupture while taking Lapelga®. A ruptured spleen can cause death. Call your doctor right away if you have pain in the left upper stomach area or left shoulder tip area.

- If you have a sickle cell trait or sickle cell disease, make sure that you tell your doctor before you start taking Lapelga® so that the potential risks and benefits can be discussed. In patients with sickle cell trait or sickle cell disease, severe sickle cell crises have been associated with the use of pegfilgrastim. Severe sickle cell crises, in some cases resulting in death, have also been associated with filgrastim, the parent compound of pegfilgrastim.

What is Lapelga® used for?
Lapelga® is used to treat neutropenia (nu-tro-**peen**-ee-ah). Neutropenia is a condition where the body makes too few white blood cells and which may be caused by drugs used to treat cancer. Neutropenia is the most serious common side-effect of chemotherapy. Neutropenia predisposes your body to infections and prevents you from fighting them. Your doctor has decided to prescribe Lapelga® for you to increase the number of neutrophils, which will fight infections.

How does Lapelga® work?
Lapelga® works by stimulating the bone marrow to make white blood cells. To make sure Lapelga® is working, your doctor may ask that you have regular blood tests to count the number of white blood cells. It is important to follow the doctor's instructions about these tests.

What are the ingredients in Lapelga®?
Medicinal ingredients: pegfilgrastim
Non-medicinal ingredients: polysorbate 20, sodium acetate, sorbitol, and water for injection.

The needle cover on the pre-filled syringe contains a derivative of latex (dry natural rubber), which should not be handled by persons sensitive to this substance.

Lapelga® comes in the following dosage forms:
A single-use pre-filled syringe containing 6 mg per 0.6 mL of pegfilgrastim active substance with

a BD UltraSafe Plus™ Passive Needle Guard. Each blister packaged syringe is provided in a carton.

Do not use Lapelga® if:

- You are allergic to pegfilgrastim, filgrastim, any of the ingredients of Lapelga®, or to other products made using the bacteria *Escherichia coli*. Talk to your doctor if you have any questions about this information.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Lapelga®. Talk about any health conditions or problems you may have, including:

- If you have common signs of infection, such as fever, chills, rash, sore throat, diarrhea, or redness, swelling, or pain around a cut or sore. If you notice any of these symptoms during treatment with Lapelga®, tell your doctor or nurse immediately. Lapelga® can reduce the risk of infection, but it may not prevent all infections. An infection can still happen during the short time when your white blood cell levels are low.
- If there is a lump, swelling, or bruising at the injection site that does not go away, talk to your doctor. Occasionally a problem may develop at the injection site.
- If you have sickle cell trait or sickle cell disease, tell your doctor prior to treatment. If you develop left upper abdominal pain or pain at the tip of your shoulder, tell your doctor or nurse immediately.

Other warnings you should know about:
Your doctor will decide if you are able to give yourself a subcutaneous (i.e., under the skin) injection. Lapelga® should only be injected on the day the doctor has determined for you, and should not be injected until 24 hours after receiving your last dose of chemotherapy in each cycle.

If you are injecting someone else with Lapelga®, it is important that you inform yourself about Lapelga® to know how and when to give the Lapelga® injection.

More information about Lapelga® is available in the Product Monograph. Any questions should be discussed with your doctor.

Pregnancy or breast feeding and Lapelga®
Lapelga® has not been studied in pregnant women, and its effects on developing babies are not known. It is possible that Lapelga® can get into human breast milk. If you are pregnant, plan to become pregnant, think you may be pregnant, or are breast feeding, you should consult your doctor before using Lapelga®.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Lapelga®:
Drug interactions between Lapelga® and other drugs have not been studied. Drugs such as lithium may affect the release of neutrophils into the blood stream. Patients taking lithium may need more frequent blood tests. You should discuss your treatment with your doctor before using Lapelga®.

How to take Lapelga®:

Usual dose:
The recommended dose of Lapelga® is a single subcutaneous injection, just under the skin, of 6 mg (the contents of one pre-filled syringe), administered once per cycle of chemotherapy. You must wait at least 24 hours after your course of cancer chemotherapy before injecting Lapelga®.

Overdose:

If you think you have taken too much Lapelga®, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:
As there should be a two-week period between Lapelga® and your next course of cancer chemotherapy, if you miss a planned dose, consult your doctor before taking the missed dose.

Information on how to inject Lapelga®

This section contains information on how to give yourself an injection of Lapelga®. **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, please ask your doctor or nurse for help. **If you are giving Lapelga® to someone else, it is important that you know how to inject Lapelga®.**

Lapelga® is provided in a single-use pre-filled syringe with a BD UltraSafe Plus™ Passive Needle Guard. The needle guard is a protective mechanism which can prevent syringe re-use and accidental needle-pricks after Lapelga® has been injected. **Lapelga® should be stored in its carton to protect from light until use**.

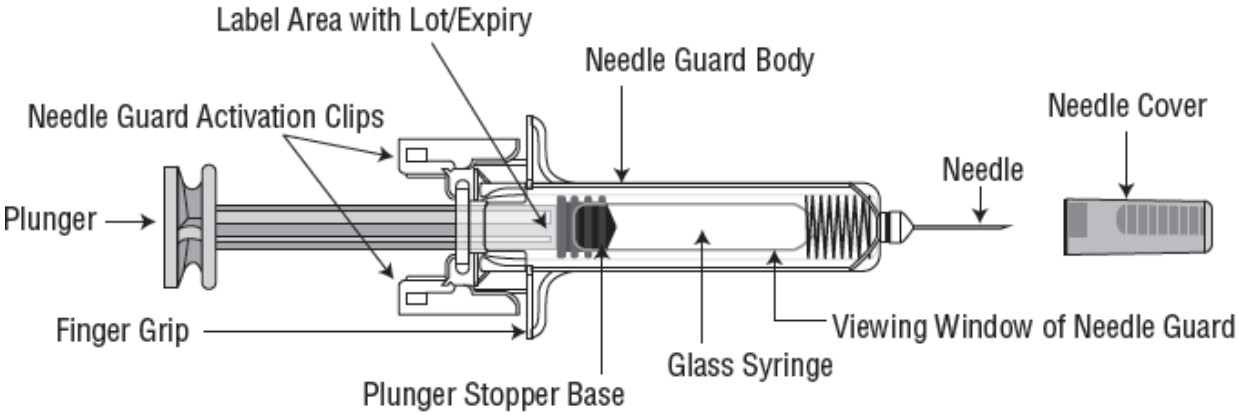
Before taking the Lapelga® injection, always check that:

- The name Lapelga® appears on the carton, blister and syringe label.
- The expiration date on the label has not passed. **You should not use a pre-filled syringe after the expiry date (see EXP) on the label.**
- The Lapelga® liquid should always be clear and colorless. Do not use Lapelga® if the contents of the pre-filled syringe appear discolored or cloudy, or if the pre-filled syringe appears to contain lumps, flakes, or particles.

Important: To help avoid possible infection, you should follow these instructions exactly.

Before Injecting Lapelga®

1. To give yourself a subcutaneous injection assemble your supplies of:
    - Lapelga® pre-filled syringe which has a plunger and a transparent (clear) plastic needle guard attached as shown in the image below:



- Alcohol wipes or similar.
- Cotton ball or gauze.
- Puncture-proof container for disposing of used syringes, as discussed with your doctor/nurse.

Setting up for an Injection

Note: The needle cover on the single-use pre-filled syringe contains dry natural rubber (latex), which should not be handled by persons sensitive to this substance.

1. Remove the carton containing the Lapelga® pre-filled syringe in the blister packaging from the refrigerator and leave it unopened on your working surface for about 30 minutes so that it reaches room temperature. **Avoid warming Lapelga® in any other way.**

2. Check the expiry date which is stated on the carton, blister and syringe label (see EXP). Do not use it if the date has passed the last day of the month shown.

3. Do not shake the pre-filled syringe as vigorous shaking may damage the medication. If the pre-filled syringe has been shaken vigorously, the solution may appear foamy and it should not be used. Check the appearance of Lapelga®. It must be clear. If it is cloudy or there are particles in it, you must not use it.

4. Clean your hands thoroughly with soap and water and/or hand sanitizer.

5. Find a comfortable, well-lit place and put the syringe, the alcohol wipes, the cotton ball or gauze and the puncture-proof container where you can reach them.

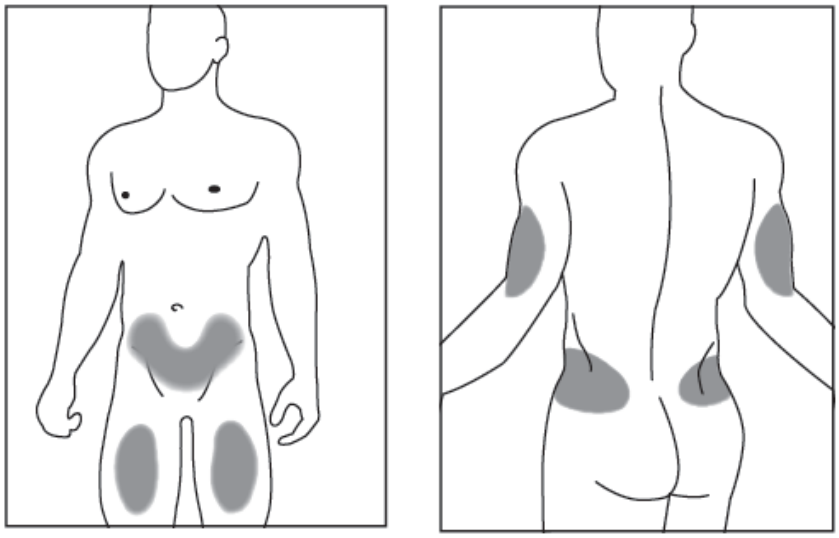
6. Keep the needle cover on the needle until you are ready to inject.

Choose an injection site

You will need to give yourself an injection into the tissue under the skin, known as a subcutaneous injection. Your doctor or nurse will tell you how frequently it should be injected. If you miss a dose, contact your doctor or nurse.

The most suitable injection sites (places on your body) to inject Lapelga® are:

- The outer area of your upper arms
- The front of your middle thighs
- The abdomen, **except for the 2 inches area around the navel**
- Upper outer area of your buttocks



From the above options, change the injection site each time you take an injection so that you do not develop soreness in one area. Do not inject into the same site that is tender, red, bruised or hard or that has scars or stretch marks.

How do I give my injection?

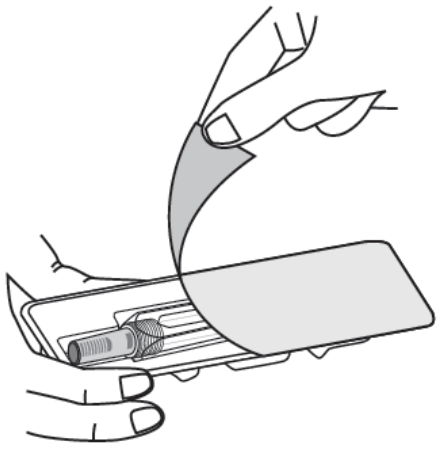
IMPORTANT: REMOVAL OF INDIVIDUAL SYRINGE FROM BLISTER PACKAGING

Follow directions for correct handling technique as shown below when removing the pre-filled syringe with the BD UltraSafe Plus™ Passive Needle Guard from the packaging, otherwise, the needle's safety mechanism may be triggered, making the syringe unusable.

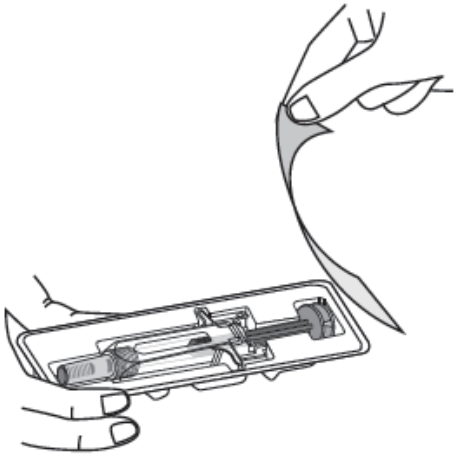
1. Locate the end of the blister packaging with the stripe as indicated by the 2 arrows and "Peel Here" on the top layer. From this end, open the blister pack by peeling back the top layer **COMPLETELY OFF**.

a.

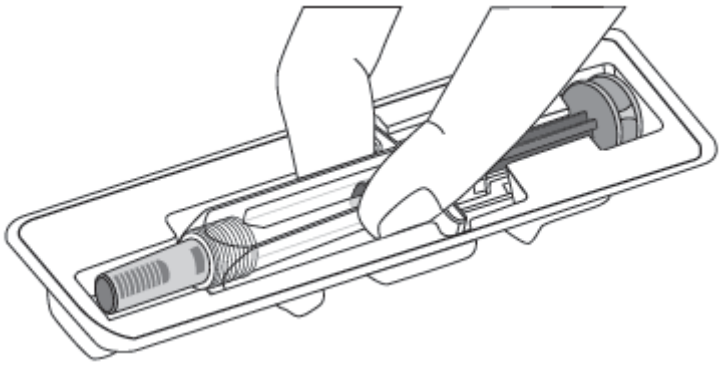
b.



c.



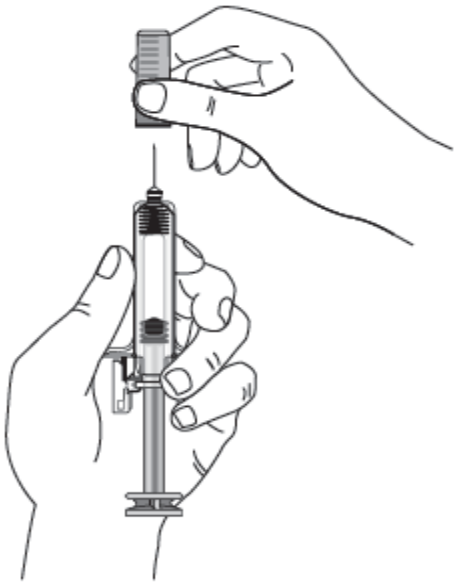
2. Remove the syringe from the blister pack **by the body** as shown below. **Do not** lift the product by the plunger or needle cover. **Do not** touch the needle guard activation clips at any time during use. This may trigger the needle's safety mechanism causing the needle to retract (pull back) before your injection is given. This will make the syringe unusable.



3. Before you inject Lapelga® you must **always clean** the skin on the selected injection site by using an alcohol wipe.

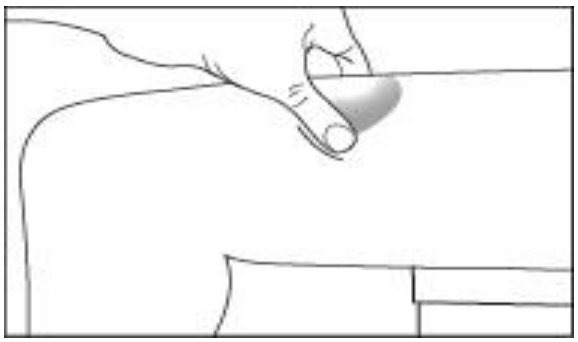
4. Hold the pre-filled syringe by the body (needle guard) with the needle pointing up and avoid

touching the needle guard activation clips. Holding the syringe by the body with the needle pointing up helps to prevent the medicine from leaking out of the needle. **Carefully pull the needle cover straight off without twisting it. Do not touch the needle or plunger. Do not use if the syringe is damaged sor needle is bent.** If the syringe is damaged or needle is bent, throw away (dispose of) the syringe in the puncture-proof container. Use a new pre-filled syringe.

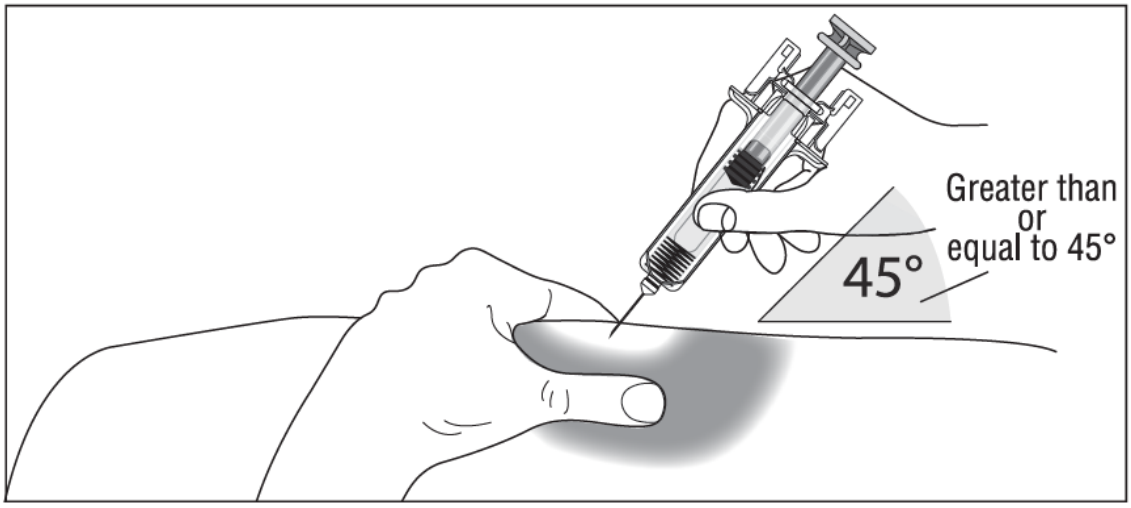


5. Do not push the plunger on the syringe before injection. This may trigger the needle's safety mechanism causing the needle to retract (pull back) before your injection is given. If any liquid is accidently expelled from the syringe do not use that pre-filled syringe. Dispose of that syringe in the puncture-proof container. Use a new pre-filled syringe.

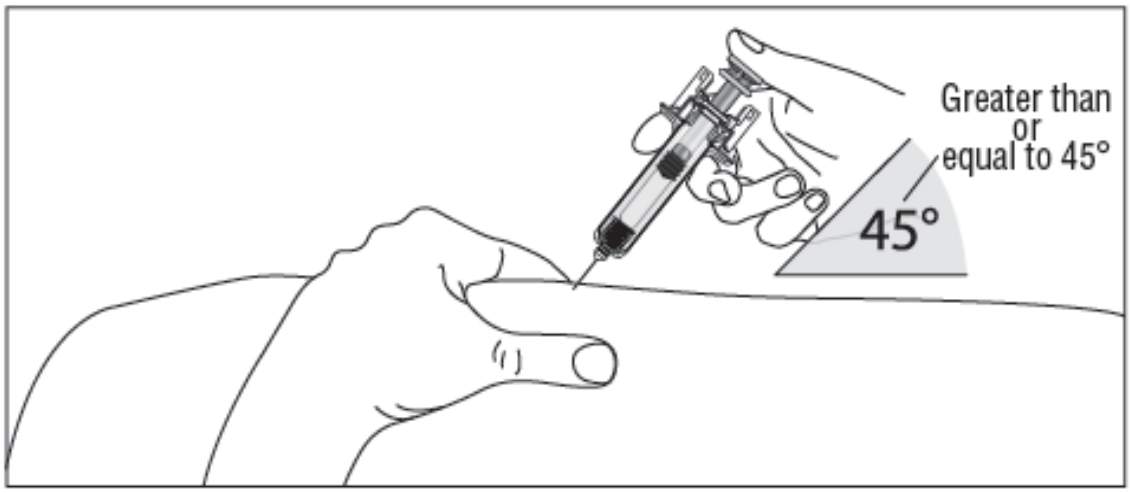
6. Hold the pre-filled syringe between the thumb and forefinger of the hand you will use to inject Lapelga®. Use the other hand to pinch a fold of the skin at the cleaned injection site between your thumb and forefinger, without squeezing it as shown below.



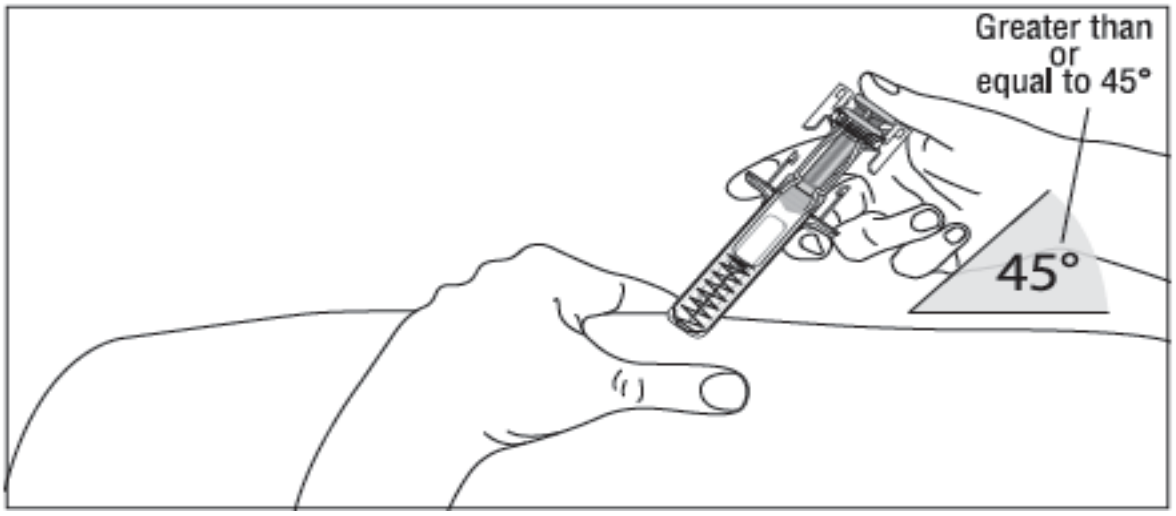
7. Insert the needle into the skin at an angle greater than or equal to 45° as shown by your doctor or nurse and the image below.



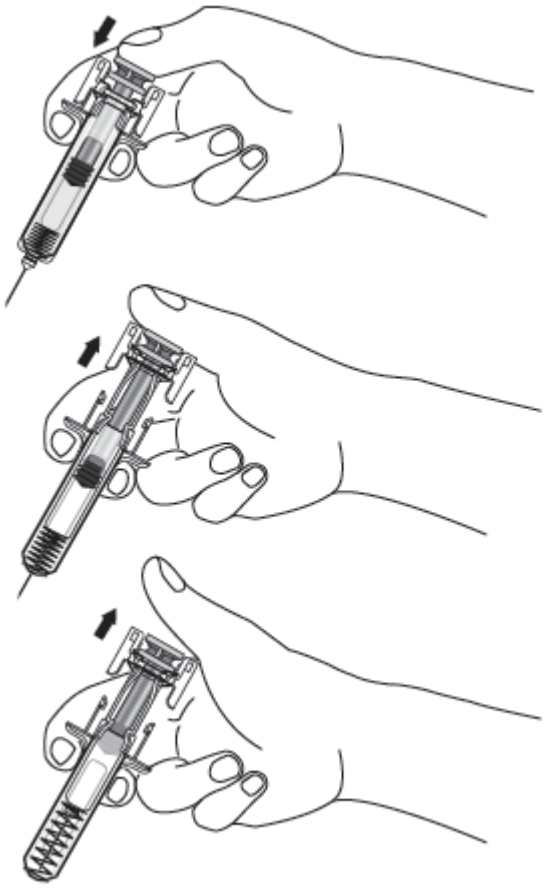
8. After the needle is inserted, let go of pinching on the fold of the skin. Inject the prescribed dose subcutaneously by pushing the plunger with your thumb while grasping the finger grips as shown in the image below and as directed by your doctor or nurse.



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



10. When the syringe is emptied of all the medication, 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.



11. After the injection, immediately place cotton or gauze on the injection site and apply pressure for several seconds. Do not use Lapelga® that is left in the syringe.

12. Place the pre-filled syringe with the needle guard covered needle into a puncture-proof container for proper disposal as described below. Use each pre-filled syringe for only one injection.

Remember
Do not hesitate to consult your doctor or nurse for help or if you have any concerns.

Disposal of Used Syringes
The used syringes should be disposed of in accordance with local requirements.

- Put used syringes into an appropriate puncture-proof container as instructed by your doctor/nurse.
- **Always** keep this container **out of reach and sight of children**.
- When the puncture-proof container is full, it should be disposed as instructed by your doctor, nurse or pharmacist. **Do not throw the container in the household trash. Do not recycle.**
- Never put used syringes into your normal household waste bin.

What are possible side effects from using Lapelga®?

These are not all the possible side effects you may feel when taking Lapelga®. If you experience any side effects not listed here, contact your healthcare professional.

- **Spleen Rupture.** Your spleen may become enlarged and can rupture while taking Lapelga®. A ruptured spleen can cause death. The spleen is located in the upper left section of your stomach area. Call your doctor right away if you have pain in the left upper stomach area or left shoulder tip area. This pain could mean your spleen is enlarged or ruptured.
- **Serious Allergic Reactions.** Serious allergic reactions can also happen. These reactions may cause a rash over the whole body, shortness of breath, wheezing, a drop in blood pressure (usually causing dizziness or lightheadedness), swelling around the mouth or eyes, fast pulse, or sweating. If you experience an allergic reaction during the injection of Lapelga®, the injection should be stopped immediately. **If at any time a serious allergic reaction occurs, immediately call a doctor or emergency services (for example, call 911).**
- **A serious lung problem called acute respiratory distress syndrome (ARDS).** Call your doctor or seek emergency care right away if you have shortness of breath, trouble breathing or a fast rate of breathing.
- **Kidney injury (glomerulonephritis)** has been seen in patients who received pegfilgrastim. Call your doctor immediately if you experience puffiness in your face or ankles, blood in your urine or brown coloured urine, or if you notice that you urinate less often than usual.

Common side effects of Lapelga®
The most common side effect that you may experience is aching in the bones and muscles. If this occurs, it can usually be relieved with a non-acetylsalicylic acid over-the-counter pain reliever. Ask your doctor which is the most suitable one for you.

Some patients experience redness, swelling, or itching at the site of injection. This may be an allergy to the ingredients in Lapelga®, or it may be a local reaction. If you notice any of these signs or symptoms, call your doctor.

Serious side effects and what to do about them		
Symptom / effect	Talk to your healthcare professional in all cases	Stop taking drug and get immediate medical help
VERY COMMON (≥ 10%)		
Bone Pain	√	
UNCOMMON (≥ 0.1% and < 1%)		
Allergic reactions [including the following symptoms: rash over the whole body, shortness of breath, a drop in blood pressure (usually causing dizziness or lightheadedness), swelling around the mouth or eyes, fast pulse, weakness, sweating; severe redness or swelling or itching at injection site]	√	√
*Splenic rupture (including the following symptoms: left upper abdominal pain or pain at the tip of your shoulder)	√	√
*Cutaneous Vasculitis (including the following symptoms: A rash in the skin surface that looks like purple or red spots or bumps, clusters of small dots, splotches or hives. Your skin may also be itchy.)	√	√
RARE (≥ 0.01% and < 0.1%)		
Acute respiratory distress syndrome (including the following symptoms: fever, shortness of breath, cough, or congestion in your lungs)	√	√
*Capillary Leak Syndrome (including the following symptoms: swelling or puffiness, which may be associated with passing water less frequently, difficulty breathing, abdominal swelling and feeling of fullness, and a general feeling of tiredness)	√	√
Kidney injury (glomerulonephritis) (including the following symptoms): puffiness in your face or ankles, blood in your urine or brown coloured urine, or if you notice that you urinate less often than usual.	√	√

* No serious events were reported in clinical trials, frequency reflects all adverse events

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Lapelga® should be stored in the refrigerator at 2° to 8°C (36° to 46°F). Freezing should be avoided. Avoid shaking Lapelga®.
- If accidently frozen, allow Lapelga® to thaw in the refrigerator before injecting. However, if frozen a second time, DO NOT use it and contact your doctor or nurse for further instructions.
- Lapelga® 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 Lapelga® has been out at room temperature it should not be put back into the refrigerator. Any Lapelga® syringes that have been out of the refrigerator for longer than 15 days should not be used and should be disposed of in accordance with local requirements.
- Lapelga® should be protected from light, so you should keep it in its carton until you are ready to use it. Avoid leaving Lapelga® in direct sunlight.

For any questions about storage, contact your doctor or nurse.

Keep out of reach and sight of children.

If you want more information about Lapelga®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada.html). Find the Patient Medication Information on the manufacturer's website at: http://www.apotex.ca/products, or by contacting DISpedia Apotex's Drug Information Service at: 1-800-667-4708.

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9.

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