READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

[Pr]Fulphila® (pronounced FULL-FIL-A)

Sterile Pegfilgrastim Solution for Injection

Read this carefully before you start taking **Fulphila** 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 **Fulphila**.

Fulphila 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 Fulphila. 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 Fulphila 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 Fulphila used for?
Fulphila 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 Fulphila for you to increase the number of neutrophils, which will fight infections.

FULPHILA is a man-made, long-acting form of granulocyte colony-stimulating factor (G-CSF), a substance naturally produced by the body.

How does Fulphila work?
Fulphila works by stimulating the bone marrow to make white blood cells. To make sure Fulphila 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 Fulphila?
Medicinal ingredients: pegfilgrastim
Non-medicinal ingredients: polysorbate 20, sodium acetate, sorbitol, and water for injection.

Fulphila comes in the following dosage forms:
Prefilled syringes containing 6 mg (10 mg/mL) of pegfilgrastim.

Syringe components are not made with natural rubber latex.

Do not use Fulphila if:
You are allergic to pegfilgrastim (Fulphila), filgrastim, any of the ingredients of Fulphila, or to other products made using the bacteria *Escherichia coli* should not take Fulphila. 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 Fulphila. 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 Fulphila, tell your doctor or nurse immediately. Fulphila 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 (ie, under the skin) injection. Fulphila 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 Fulphila, it is important that you inform yourself about Fulphila to know how and when to give the Fulphila injection.

Make sure your doctor knows about all medications you are taking before starting Fulphila injections. Patients taking lithium may need more frequent blood tests.

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

Pregnancy or breast feeding and Fulphila

Fulphila has not been studied in pregnant women, and its effects on developing babies are not known. It is possible that Fulphila 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 Fulphila.

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 Fulphila:
Drug interactions between Fulphila and other drugs have not been studied. Drugs such as lithium may affect the release of neutrophils into the blood stream. You should discuss your treatment with your doctor before using Fulphila.

How to take Fulphila:
Fulphila is available in a prefilled syringe. Fulphila should be stored in its carton to protect it from light until use. If you are giving someone else Fulphila injections, it is important that you know how to inject Fulphila.

Before a Fulphila injection is given, always check to see that:

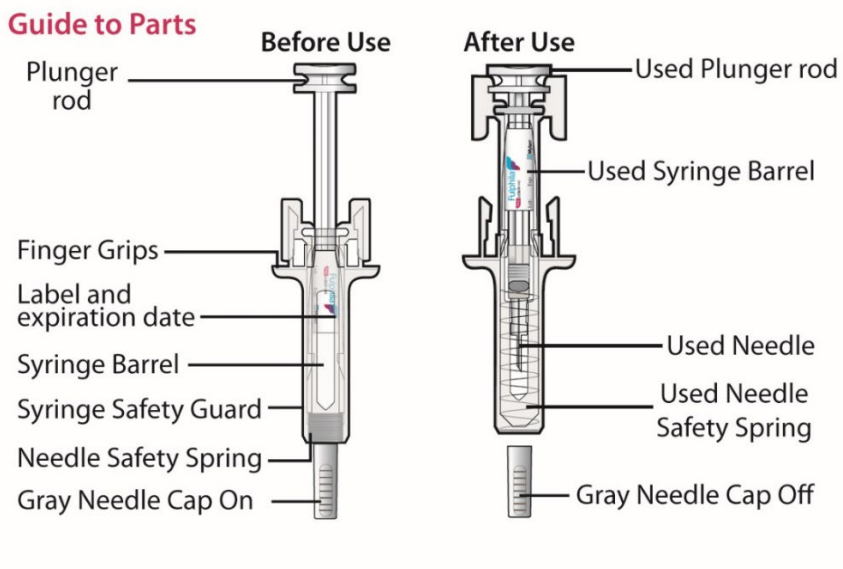
- The name Fulphila appears on the dispensing pack and prefilled syringe label.
- The expiration date on the prefilled syringe has not passed.

You should not use a prefilled syringe after the expiry date on the label.

The Fulphila liquid should always be clear and colourless. Do not use Fulphila if the contents of the prefilled syringe appear discolored or cloudy, or if the prefilled syringe appears to contain lumps, flakes, or particles.

IMPORTANT: TO HELP AVOID POSSIBLE INFECTION, FOLLOW THESE INSTRUCTIONS EXACTLY.

How to prepare and give a Fulphila injection



Important: The needle is covered by the gray needle cap before use.

Important Information

Before you use a Fulphila® prefilled syringe with automatic needle guard, read this important information:

- It is important that you do not try to give yourself the injection unless you have received training from your doctor or healthcare provider.
- Fulphila® is given as an injection into the tissue just under the skin (subcutaneous injection).
- Call your doctor or healthcare provider if you have any questions.
- **Keep prefilled syringes out of the reach of children.**

x **Do not** shake the prefilled syringe. If the prefilled syringe has been shaken vigorously, the solution may appear foamy and it should not be used.
x **Do not** use the prefilled syringe if the carton is open or damaged.

x **Do not** remove the gray needle cap from the prefilled syringe until you are ready to inject.
x **Do not** use the prefilled syringe if it has been dropped on a hard surface. The syringe may be broken even if you cannot see the break. Use a new prefilled syringe.
x **Do not** attempt to activate the prefilled syringe prior to injection.
x **Do not** attempt to remove the clear prefilled syringe safety guard from the prefilled syringe.
x **Do not** attempt to remove the label from the prefilled syringe barrel before administering your injection.

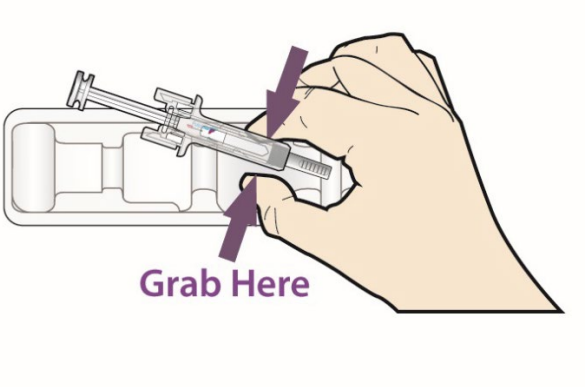
Storage
Store Fulphila® in the refrigerator between 2ºC to 8ºC (36ºF to 46ºF). **Do not** freeze. Keep the prefilled syringe in the original carton to protect from light or physical damage. If Fulphila® is accidentally frozen, allow it to thaw in the refrigerator before injecting. **Do not** try to warm it by using a heat source such as hot water or a microwave. However, if it is frozen a second time, **do not** use. Throw away (dispose of) any Fulphila® that has been left at room temperature, 20ºC to 25ºC (68ºF to 77ºF), for more than 72 hours. **Do not** leave Fulphila® in direct sunlight. For all questions about storage, contact your doctor, nurse, or pharmacist.

Step 1: Gather supplies

A - Find a clean, well-lit and flat working surface, such as a table.
B - Take the prefilled syringe out of the refrigerator 30 minutes before use and allow it to reach room temperature before giving an injection. Put any remaining prefilled syringes back in the refrigerator.
C - Make sure the name Fulphila® appears on the carton and prefilled syringe label and that the dose strength is 6 mg/ 0.6 mL.
D - Remove the prefilled syringe tray from the carton.
E - Gather the supplies for the injection: alcohol wipes, a cotton ball or gauze pad and an approved sharps disposal container.
F - Wash hands thoroughly with soap and water.

Step 2: Prepare for injection

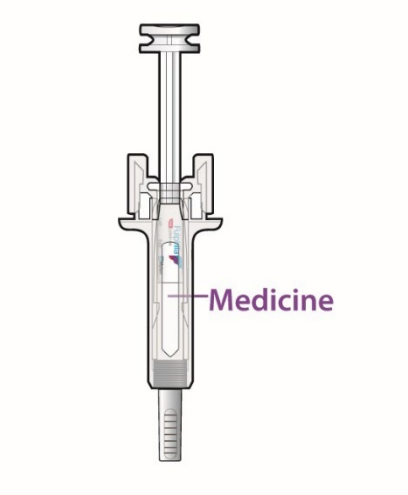
A - Open the tray by peeling away the cover. Grab the prefilled syringe safety guard to remove the prefilled syringe from the tray.



For safety reasons:

× **Do not** grab the plunger rod.
× **Do not** grasp the gray needle cap.

B - Inspect the medicine and prefilled syringe. **It must be a clear and colorless liquid.**

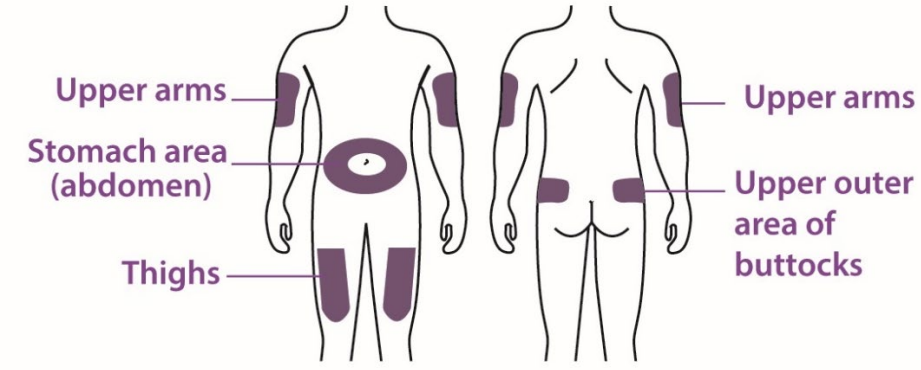


Do not use the prefilled syringe if:

- The medicine is cloudy or discolored, or contains flakes or particles.
- The prefilled syringe has been dropped.
- Any part appears cracked or broken.
- The gray needle cap is missing or not securely attached.
- The expiration date printed on the label has passed.

In all cases, use a new prefilled syringe and call your healthcare provider.

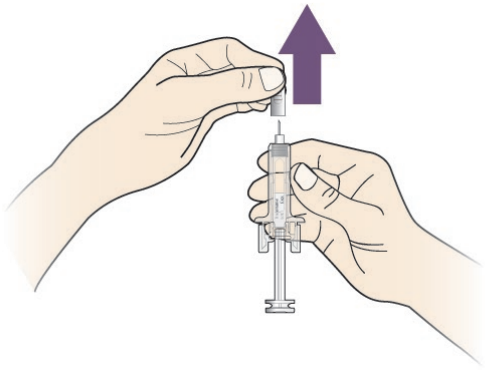
C - Clean the injection site with an alcohol wipe. Let the skin dry.
There are four recommended injection sites: The thigh; the stomach area (abdomen), except for a **2**-inch area right around the navel (belly button); the upper outer area of the buttocks (only if someone else is giving you the injection); and the outer area of the upper arm (only if someone else is giving you the injection).



× **Do not** touch this area again 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.

- If you want to use the same injection site, make sure it is not the same spot on the injection site you used for a previous injection.

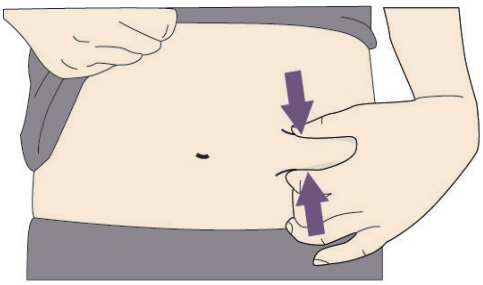
D - Hold the prefilled syringe by the safety guard. When ready, carefully pull the gray needle cap straight off and away from the body.



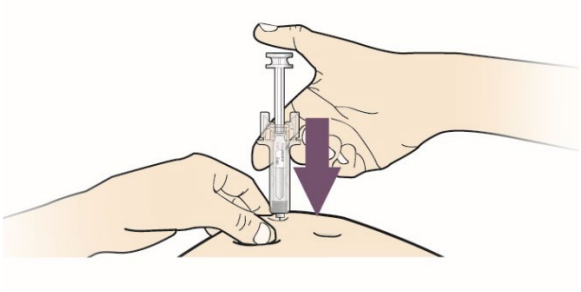
× **Do not** twist or bend the gray needle cap.
× **Do not** hold the prefilled syringe by the plunger rod.
× **Do not** put the gray needle cap back onto the prefilled syringe.

Step 3: Inject the dose

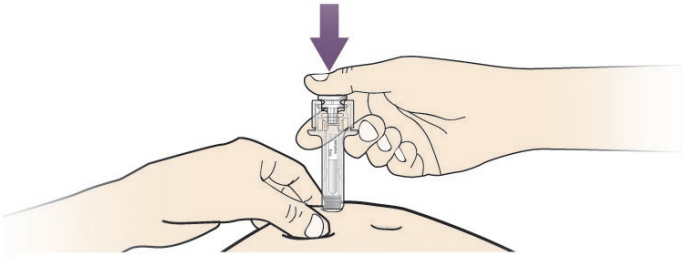
A - Pinch the cleaned injection site to create a firm surface. **Keep skin pinched while injecting.**



B - Hold the pinch. Insert the needle into the skin between 45 to 90 degrees.
× **Do not** touch the cleaned area of the skin.



C - Using slow and constant pressure, push the plunger rod until it reaches the bottom. **The plunger must be pushed fully in order to administer the full dose.**

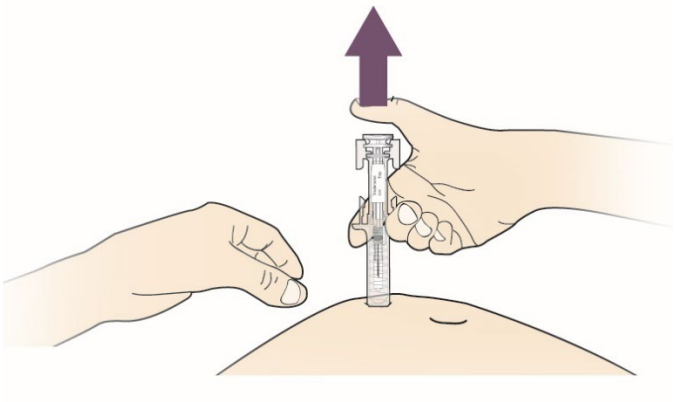


D - Once the entire dose has been delivered, the needle safety guard will be triggered and either of the following actions can be followed:

- Release the plunger until the entire needle is covered and then remove the needle from the injection site.

Or

- Gently remove the needle from the injection site and release the plunger until the entire needle is covered by the guard.



After releasing the plunger, the prefilled syringe safety guard will safely cover the injection needle.

- Once the needle has been removed from the injection site dispose of the syringe as per Step 4.

- **If the guard is not activated or only partially activated, discard the product (without replacing the needle cap) as in Step 4.**

- **If your injection is given by another person, he or she should also be careful when removing the needle from your skin in order to prevent accidental needlestick injury and possible infections.**

- **When you remove the syringe, if it looks like the medicine is still in the syringe barrel, this means you have not received the full dose. Call your healthcare provider right away.**

E - Examine the injection site. If there is blood, press a cotton ball or gauze pad on the injection site. Do not rub the injection site. Apply an adhesive bandage if needed.

Step 4: Dispose of supplies

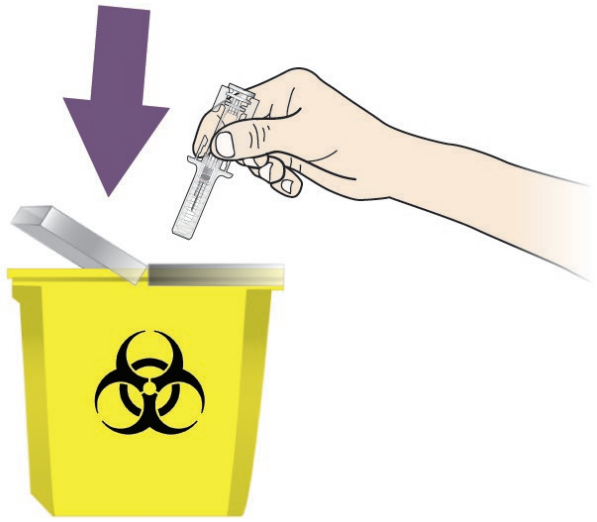
A - Put the used prefilled syringe and other supplies in an approved sharps disposal container right away after use. Do not throw away the syringe in the household garbage.

- If you do not have an approved sharps disposal container, you may use a household container that is:
  - Made of heavy-duty plastic
  - Can be closed with a tight-fitting, puncture-resistant lid without sharps being able to come out
  - Upright and stable during use
  - Leak-resistant
  - Properly labeled to warn of hazardous waste inside the container
  - **Do not** use glass or clear plastic containers.

B - When your sharps disposal container is almost full, you will need to tape around the cap or lid and:

- Check with your doctor, nurse, or pharmacist for instructions on how to properly dispose of the filled container.

Do not throw the container in household garbage. Do not recycle.



Important: Keep the syringe and sharps disposal container out of the reach of children.
× **Do not** reuse the prefilled syringe.
× **Do not** recycle prefilled syringes or throw them into household waste.

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

Overdose:

If you think you, or a person you are caring for, have taken too much Fulphila, 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 Fulphila and your next course of cancer chemotherapy, if you miss a planned dose, consult your doctor before taking the missed dose.

What are possible side effects from using Fulphila?

These are not all the possible side effects you may experience when taking Fulphila. 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 Fulphila. 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 Fulphila, 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.

What are the most common side effects of Fulphila?
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 Fulphila, 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		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON (≥ 0.1% and < 1%)			
Bone Pain		√	
Low platelet counts (thrombocytopenia) (including the following symptoms: easy bruising and increased bleeding).		√	
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		√	√
Acute respiratory distress syndrome (including the following symptoms: fever, shortness of breath, cough, or congestion in your lungs)		√	√
VERY RARE < 0.01%)			
Splenomegaly (including the following symptoms: pain		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
in the left upper stomach area or left shoulder tip area)			
***FREQUENCY NOT KNOWN**			
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.)		√	
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.		√	√
**Abnormal number of immature bone marrow cells (myelodysplastic syndrome) that could lead to a type of cancer (acute myeloid leukemia) (including the following symptoms: fever, bone pain, bruising, difficulty breathing, bleeding and a general feeling of tiredness).		√	√

*Reported in the post-marketing setting where the incidence is not known.
**Adverse events in breast and lung cancer patients receiving chemotherapy and/or radiotherapy

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.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:
Fulphila should be stored in the refrigerator at 2° to 8°C (36° to 46°F), but not in the freezer. Keep the container in the outer carton to protect from light. Avoid shaking Fulphila. If Fulphila is accidentally frozen, allow it to thaw in the refrigerator before injecting. However, if it is frozen a second time, do not use it and contact your doctor or nurse for further instructions. Fulphila can be left out at room temperature for up to 72 hours. Keep out of reach and sight of children. For any questions about storage, contact your doctor or nurse.

If you want more information about Fulphila:

- 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/services/drugs-health-products/drug-products/drug-product-database.html); by calling 1-833-986-1468 or medical.informationCanada@biocon.com

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