

Part III: CONSUMER INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE PATIENT MEDICATION INFORMATION

PLEGRIDY[®] (pronounced PLEGG-rih-dee)
(peginterferon beta-1a)

solution for injection, for subcutaneous use in a single use, pre-filled pen/pre-filled syringe

Read this carefully before you start taking **PLEGRIDY** and each time you get a refill of your prescription. This leaflet is a summary and will not tell you everything about this drug. Talk to your doctor or nurse about your medical condition and treatment and ask if there is any new information about **PLEGRIDY**.

What is PLEGRIDY used for?

The active substance in **PLEGRIDY** is peginterferon beta-1a. Peginterferon beta-1a is a long-acting form of interferon. Interferons are natural substances made in your body to help protect you from infections and diseases. **PLEGRIDY** is intended for use under the guidance and supervision of a physician familiar with the treatment of MS.

Multiple Sclerosis (MS) is a long term illness that affects the central nervous system (CNS), including the brain and spinal cord. In multiple sclerosis, your body's immune system damages the protective covering (myelin) that surrounds the nerves in your brain and spinal cord. This disrupts the messages between the brain and other parts of the body causing the symptoms of MS.

Everyone has their own set of MS symptoms. These can include:

- feeling off-balance or light headed, walking problems, stiffness and muscle spasms, tiredness, numbness in the face, arms or legs
- acute or chronic pain, bladder and bowel problems, sexual problems and problems with vision
- difficulty in thinking and concentrating, depression.

MS symptoms also tend to flare up from time to time: this is called a relapse.

When it should not be used:

Do not use **PLEGRIDY**:

- If you are allergic (hypersensitive) to interferon beta, peginterferon beta-1a or any of the ingredients in **PLEGRIDY**
- If you are pregnant
- If you currently experience severe depression and thoughts about committing suicide

If you notice signs of allergy:

- Because **PLEGRIDY** is based on a protein, there is a small chance of an allergic reaction. Signs of an allergic reaction may include:

- becoming very wheezy or having difficulty breathing
- swelling around the face (lips, tongue or throat)
- skin rashes or redness

Usually these symptoms will be signs of less serious side effects. But they may be more serious.

If you know you are allergic or notice any of these symptoms contact a doctor as soon as possible.

How does PLEGRIDY work?

PLEGRIDY seems to work by stopping the body's immune system from damaging the protective covering (myelin) that surrounds the nerves in your brain and spinal cord. This can help to reduce the number of relapses that you have and slow down the disabling effects of MS. Treatment with PLEGRIDY can help to prevent you from getting worse, although it will not cure MS.

Your doctor will advise you for how long you can use PLEGRIDY or when to stop.

What are the ingredients in PLEGRIDY?

Medicinal ingredients: peginterferon beta 1a.

Non-medicinal ingredients: L-Arginine Hydrochloride, Glacial Acetic Acid, Polysorbate 20 in Water for Injection, and Sodium Acetate Trihydrate.

PLEGRIDY comes in the following dosage forms:

PLEGRIDY is a liquid for subcutaneous injection provided in a pre-filled syringe or pre-filled pen. Three strengths are available, 63 µg, 94 µg and 125 µg.

**not all dosage forms may be available*

WARNINGS AND PRECAUTIONS

BEFORE you use PLEGRIDY talk to your doctor or pharmacist if:

- you have ever experienced:
 - depression or problems affecting your mood
 - thoughts about committing suicide

Your doctor may still prescribe PLEGRIDY for you, but it's important to let your doctor know if you have had depression or any similar problems affecting your moods in the past.

- If you have:
 - serious liver problems
 - irritation at your injection site, which can lead to skin and tissue damage, (injection site necrosis). Read carefully and follow the instructions given under “How to inject PLEGRIDY” to reduce the risk of injection site necrosis
 - a low number of white blood cells or platelets, which can cause an increased risk of infection, bleeding or anaemia
 - seizure disorders, not controlled by medication
 - heart problems, which can cause symptoms such as chest pain (angina), particularly after any activity; swollen ankles, shortness of breath (congestive heart failure); or an irregular heartbeat (arrhythmias)

PLEGRIDY may affect your white blood cell counts and your liver function. Your doctor may periodically do a blood test to count the number of your white blood cells or platelets and to check that your liver is working properly.

While you are using PLEGRIDY talk to your doctor or pharmacist if:

- There are changes to your mood, for example you have thoughts about suicide; feel unusually sad, anxious or worthless.

Tell your doctor, nurse or pharmacist about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Sometimes you will need to remind other medical staff that you are being treated with PLEGRIDY. For example, if you are prescribed other medicines, or if you have a blood test, PLEGRIDY may affect the other medicines or the test result.

Pregnancy and breastfeeding and fertility:

Before starting PLEGRIDY speak to your doctor if you are pregnant or plan to become pregnant. If you could get pregnant, you need to use contraception while you use PLEGRIDY. If you are planning a baby or if you do become pregnant while you are using PLEGRIDY, tell your doctor. You and your doctor can discuss if you should carry on with treatment. If you are already pregnant, or think that you might be, talk to a doctor as soon as you can. If you want to breastfeed talk to your doctor first.

How to take PLEGRIDY:

Usual dose:

PLEGRIDY is only to be injected once every two weeks. PLEGRIDY is injected under the skin (subcutaneously). Try to use PLEGRIDY at the same time on the same day every time you inject.

Starting PLEGRIDY

If you are new to PLEGRIDY, your doctor may advise you to gradually increase your dose so that you can adjust to the side effects of PLEGRIDY before taking the full dose. You will be provided with a Starter Pack containing your first 2 injections: one orange labelled syringe/pen with PLEGRIDY 63 micrograms (for day 0) and one blue labelled syringe/pen with PLEGRIDY 94 micrograms (for day 14). After that you will be provided with a maintenance pack containing grey pens/syringes with PLEGRIDY 125 micrograms (for day 28 and then every 2 weeks). Read the instructions on how to inject before you start using PLEGRIDY.

Use the record table printed on the inside lid of the Pack to keep track of your injection dates.

Injecting yourself

Only inject PLEGRIDY by yourself once you have been trained by a healthcare professional. Read and follow the advice given in the instructions on how to inject yourself before you start.

If you have trouble handling the pen or syringe, ask your doctor or nurse who will be able to assist you.

How long to use PLEGRIDY

Your doctor will tell you how long you need to keep using PLEGRIDY. It is important to continue using PLEGRIDY regularly. Do not make changes unless your doctor tells you.

Children and adolescents

PLEGRIDY has not been tested in children and adolescents below 18 years old.

Elderly

PLEGRIDY has not been tested in people older than 65 years old. If you are over 65 your doctor may still prescribe PLEGRIDY.

Overdose:

You must only inject PLEGRIDY once every 14 days (every 2 weeks).

If you have used more than one injection of PLEGRIDY in a 7-day period, contact your doctor or nurse straight away.

If you think you have taken too much PLEGRIDY, contact your doctor or nurse, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

You need to inject PLEGRIDY once every 14 days (every 2 weeks). This regular schedule helps to deliver the treatment as evenly as possible.

If you do miss your usual day, inject as soon as you can and carry on as usual. However, never inject more than once in a 7-day period. Do not use two injections to make up for a missed dose. If you have problems with your dosing schedule, talk to your doctor or nurse.

What are possible side effects from using PLEGRIDY?

These are the side effects that people reported when PLEGRIDY was being tested. The figures are based on how many people reported these events. It gives you an idea how likely you are to get similar side effects.

Very common side effects

(at least 1 in 10 people are affected)

Flu-like symptoms

These symptoms are not really the flu.

You can't pass it on to anyone else. They are more common symptoms when you first start using PLEGRIDY. Using the Starter Pack to gradually increase the amount of PLEGRIDY you inject when you start treatment can help reduce symptoms. As you keep using your injections, the flu-like symptoms gradually get less.

Three simple ways to help reduce the impact of flu-like symptoms:

1. Consider the timing of your PLEGRIDY injection. The start and end of flu-like symptoms are different for every patient. Use your PLEGRIDY injection just before bed time. This may allow you to sleep through the effects.

2. Take acetaminophen or ibuprofen half an hour before your PLEGRIDY injection. Speak to your doctor or pharmacist about how much to take and how long to take it.
3. If you have a fever, drink plenty of water to keep you hydrated.

Injection site reactions

You may get reactions around the place you inject. These usually get less over time. To reduce injection site reactions;

- Alternate the sites you use for injections
- Do not use the same injection site for consecutive injections
- After injecting, check the site for redness, swelling, or tenderness

If you have a skin reaction and it does not clear up in a few days, contact your doctor or nurse. Read and follow the advice given in the instructions on How to inject PLEGRIDY.

Changes to levels of liver enzymes

These changes will show up in blood tests. You may not experience any symptoms or you may notice:

- Yellowing of your skin or the whites of your eyes (jaundice)
- Itching all over
- Feeling sick, being sick (nausea and vomiting)
- Easy bruising of the skin.

Call a doctor immediately if you do get any of these symptoms. They may be signs of a possible liver problem.

Less common side effects reported in association with interferon beta include:

Respiratory System: shortness of breath, tiredness, chest tightness or pain (pulmonary arterial hypertension).

If any of the effects trouble you, talk to your doctor.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Common		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
Symptom / Effect		Only if severe	In all cases	
Flu-like symptoms	Headache, muscle aches, chills or a fever	X		
Injection site reactions	Redness, itching or pain	X		
	Swelling, bruising, warmth or rash at injection site	X		

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Changes to levels of liver enzymes	Yellowing of your skin or the whites of your eyes (jaundice)		X	
	Itching all over		X	
	Feeling sick, being sick (nausea and vomiting)		X	
	Easy bruising of the skin		X	
Other	Headache	X		
	Muscle pain (myalgia)	X		
	Pain in your joints, arms, legs or neck (arthralgia)	X		
	Chills, feeling cold	X		
	Feeling weak and tired (asthenia)	X		
	Feeling sick or being sick (nausea or vomiting)	X		
	Itchy skin (pruritus)	X		
	Increase in body temperature	X		

This is not a complete list of side effects. For any unexpected effects while taking PLEGRIDY, contact your doctor or pharmacist.

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 doctor or nurse.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](#);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 1908C
Ottawa, ON
K1A 0K9Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available at [MedEffect](#).

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:

Keep this medicine out of the sight and reach of children.

Do not use after the expiry date stated on the carton. The expiry refers to the last day of the month.

Keep PLEGRIDY syringes and pens in the outer carton in the refrigerator (between 2°C and 8°C). If a refrigerator is not available, PLEGRIDY can be left at room temperature 2°C to 25°C for up to 30 days. Keep the outer carton closed to protect PLEGRIDY from light. Do not freeze.

PLEGRIDY does not contain preservatives.

Do NOT use PLEGRIDY if you notice any of the following:

- If the pre-filled pen or syringe is broken.
- If the solution is coloured or you can see particles floating in it.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Disposal:

Ask your pharmacist how to dispose of used pens/syringes and any unused medicines. Dispose of any unused medicine according to community guidelines. Pens/syringes should not be disposed of in a recycling bin.

INSTRUCTIONS FOR USE
PLEGRIDY® (pronounced PLEGG-rih-dee)
(peginterferon beta-1a)

Solution for injection, for subcutaneous use, pre-filled syringe

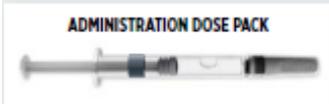
Read the Instructions for Use before you start using PLEGRIDY and each time you get a refill of your prescription. There may be new information. This information does not take the place of talking to doctor or nurse about your medical condition or your treatment.

Note:

- **Before you use the PLEGRIDY pre-filled syringe for the first time**, your doctor or nurse should show you how to prepare and inject your PLEGRIDY pre-filled syringe the right way.
- If you experience difficulty or have questions about how to inject, call the Biogen ONE® Support Program at 1-855-676-6300.
- PLEGRIDY pre-filled syringe is for use under the skin only (subcutaneous).
- Each PLEGRIDY pre-filled syringe can be used 1 time only.
- **Do not** share your PLEGRIDY pre-filled syringe with anyone else to avoid giving an infection to them or getting an infection from them.
- **Do not** use more than 1 pre-filled syringe every 14 days (every 2 weeks).
- **Do not** use your PLEGRIDY pre-filled syringe if it has been dropped or visibly damaged.

DOSE SCHEDULE

Choose the correct PLEGRIDY pre-filled syringe from a pack. PLEGRIDY pre-filled syringe Starter Pack contains your first two injections to gradually adjust your dose.

WHEN	WHICH DOSE	WHICH PACK
Day 0* (63 micrograms)	First injection: 63 micrograms, choose orange labelled syringe	 <p style="text-align: center;">STARTER PACK</p>
Day 14* (94 micrograms)	Second injection 94 micrograms, choose blue labelled syringe	
Day 28* and then every 2 weeks after (125 micrograms)	Full dose injection: 125 micrograms, choose grey labelled syringe	 <p style="text-align: center;">ADMINISTRATION DOSE PACK</p>

**Do not use more than one pre-filled syringe per 14-day period (every 2 weeks).*

Supplies needed for your PLEGRIDY injection:

- 1 PLEGRIDY pre-filled syringe (see Figure A)

Before Use-Parts of your PLEGRIDY pre-filled syringe (Figure A)

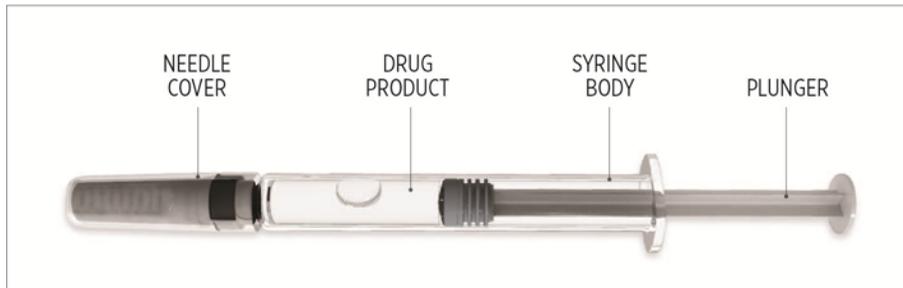


Figure A

Additional supplies which are not included in the pack (see Figure B):

- Alcohol wipe
- Gauze pad
- Adhesive bandage
- 1 sharps container for throwing away used needles and PLEGRIDY pre-filled syringes. See “Disposing of Your Used PLEGRIDY pre-filled Syringes” at the end of these instructions.
- A well-lit area and clean flat surface to work on, like a table.



Figure B

Preparing for Your Injection

Step 1: Remove your pre-filled syringe from the refrigerator

- a) Remove your PLEGRIDY pack from the refrigerator and select the appropriate pre-filled syringe (dosage) from the pack.
- b) Close the pack and put back in the refrigerator after removing one pre-filled syringe.
- c) **Let the PLEGRIDY pre-filled syringe come to room temperature for at least 30 minutes.**

 **Do not** use external heat sources such as hot water to warm the PLEGRIDY pre-filled syringe.

Step 2: Collect your supplies and wash your hands

- a) Find a well-lit, clean flat surface to work on, like a table. Collect all the supplies you will need to give yourself or to receive an injection
- b) Wash your hands with soap and water and dry thoroughly.

Step 3: Check your PLEGRIDY pre-filled syringe

- a) Check the expiration date printed on your PLEGRIDY pre-filled syringe (See Figure C)
 - Check that your PLEGRIDY medicine is clear and colourless (see Figure D).
 - ⚠ **Do not** use external heat sources, such as hot water, to warm your pre-filled syringe.
 - It is past the expiration date.
 - The liquid is cloudy, or has floating particles in it.



Note you might see air bubbles in your PLEGRIDY medicine. This is normal and does not need to be expelled prior to your injection.

Giving the Injection

Step 4: Choose and clean the injection site

- a) PLEGRIDY pre-filled syringe is for subcutaneous injection (injection into the skin).
- b) PLEGRIDY pre-filled syringe should be injected into the abdomen, thigh, or the back of the upper arm. (See Figure E).

- ⚠ **Do not** inject directly into your belly button.
- ⚠ **Do not** inject into an area of the body where the skin is irritated, tender, red, bruised, tattooed, infected or scarred.
- c) Choose an injection site and wipe the skin with an alcohol wipe.
- d) Let the injection site dry before injecting the dose.
- ⚠ **Do not** touch this area again before giving the injection.

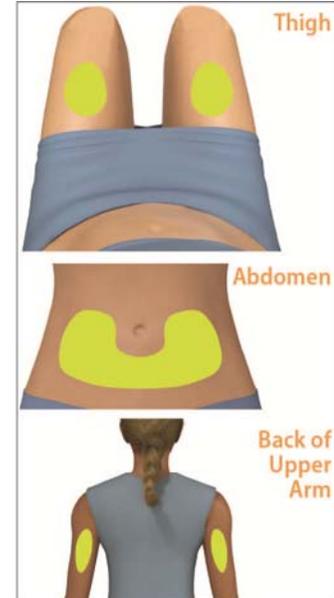


Figure E

Giving Your injection

Step 5: Firmly Remove Needle Cover

- a) Pull the needle cover straight off the needle and dispose of the needle cover (See Figure F).

⚠ Use caution when removing the needle cover to avoid getting a needle stick injury.

⚠ Do not touch the needle.

⚠ Caution – do not recap the PLEGRIDY pre-filled syringe. You could get a needle stick injury.



Figure F

Step 6: Gently Pinch the Injection Site

- a) Gently pinch the skin around the cleaned injection site using thumb and forefinger to create a slight bulge or fold. (see figure G).



Figure G

Step 7: Give Your Injection

- a) Hold the PLEGRIDY pre-filled syringe at a 90° angle to the injection site. Quickly insert the needle straight into the skin fold until the needle is fully under the skin (See Figure H).
- b) After the needle is in, let go of your skin.

⚠ Do not pull back on the plunger.

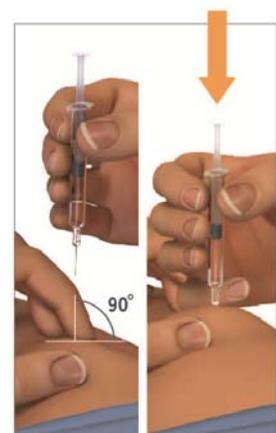


Figure H

- c) Slowly push the plunger all the way down until the syringe is empty. (See Figure I).

⚠ Do not take your PLEGRIDY pre-filled syringe out of the injection site until you have pushed the plunger all the way down.



Figure I

- d) Keep the needle in for 5 seconds (See Figure J).



Figure J

Step 8: Remove your PLEGRIDY pre-filled syringe from your injection site

- a) Pull the needle straight out. (See Figure K)

⚠ Caution – do not recap the PLEGRIDY pre-filled syringe. You could get a needle stick injury.

⚠ Do not reuse the PLEGRIDY pre-filled syringe.

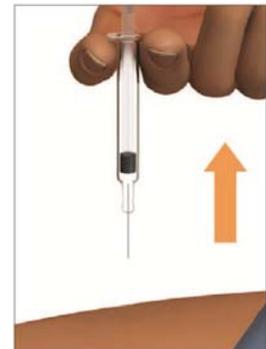


Figure K

After your Injection

Step 9: Dispose of your used PLEGRIDY pre-filled syringe

- a) Throw away the used PLEGRIDY pre-filled syringe into a special secure container, such as a sharps bin, or according to community guidelines. Check with your doctor, pharmacist or nurse about the right way to throw away the container.

 **Do not** dispose of your used pre-filled syringe or disposal container in your household trash unless your community guidelines permit this.

Step 10: Care of your injection site

- a) If needed, apply a gauze pad or adhesive bandage to the injection site.

Step 11: Check your injection site

- a) After 2 hours, check the injection site for redness, swelling, or tenderness.
- b) If you have a skin reaction and it does not clear up in a few days, contact your doctor or nurse.

General Warnings

 **Do not** reuse your PLEGRIDY pre-filled syringe.

 **Do not** share your PLEGRIDY pre-filled syringe.

- a) Keep PLEGRIDY pre-filled syringe and all medications out of reach of children.

Record Date and Location

- a) Record the date and location of each injection and alternate sites between your injections.
- b) Do not use the same injection site for consecutive injections.

Storage

- a) Recommended storage is controlled refrigeration 2° to 8°C (36°F to 46°F) in the closed original carton to protect from light.
- b) If needed, PLEGRIDY may be stored in the closed original carton without refrigeration up to 25°C (77°F) for up to 30 days.
- c) **PLEGRIDY can be removed from and returned to the refrigerator if necessary. The total combined time out of the refrigeration should not exceed 30 days, at a temperature up to 25°C (up to 77°F).**

Do not freeze or expose to high temperatures.

INSTRUCTIONS FOR USE

PLEGRIDY® (pronounced PLEGG-rih-dee) (peginterferon beta-1a)

solution for injection, for subcutaneous injection in a single use, pre-filled pen

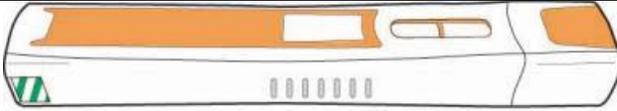
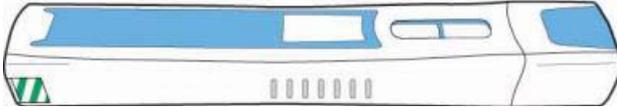
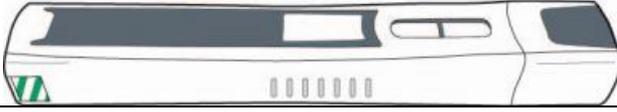
Read the Instructions for Use before you start using PLEGRIDY and each time you get a refill of your prescription. There may be new information. This information does not take the place of talking to your doctor or nurse about your medical condition or your treatment.

Note:

- **Before you use the PLEGRIDY pre-filled pen for the first time**, your doctor or nurse should show you or your caregiver how to prepare and inject your PLEGRIDY pen the right way.
- If you experience difficulty or have questions about how to inject, call the Biogen ONE® Support Program at 1-855-676-6300.
- PLEGRIDY pen is for use under the skin only (subcutaneous).
- Each PLEGRIDY pen can be used 1 time only.
- **Do not** share your PLEGRIDY pen with anyone else to avoid giving an infection to them or getting an infection from them.
- **Do not** use more than 1 pen every 14 days (every 2 weeks).
- **Do not** use your PLEGRIDY Pen if it has been dropped or visibly damaged.

DOSE SCHEDULE

Choose the correct PLEGRIDY Pen from the pack. PLEGRIDY pre-filled pen Starter Pack contains your first two injections to gradually adjust your dose.

WHEN	WHICH DOSE	WHICH PACK
Day 0* (63 micrograms)	First injection: 63 micrograms, choose orange pen	 STARTER PACK
Day 14* (94 micrograms)	Second injection 94 micrograms, choose blue pen	
Day 28* and then every 2 weeks after (125 micrograms)	Full dose injection: 125 micrograms, choose gray pen	ADMINISTRATION DOSE PACK 

**Do not use more than one pre-filled pen per 14-day period (every 2 weeks).*

REMOVE FROM REFRIGERATOR

Remove 1 PLEGRIDY pack out of the refrigerator and select the appropriate pen (dosage) from the pack. Close the pack and put back in the refrigerator after removal of the first injection pre-filled pen.

CHECK PACK AND PEN

Check the expiration date printed on the PLEGRIDY Pen, PLEGRIDY Pen carton, and the outer carton. Do not use the PLEGRIDY Pen past the expiration date.

Let the pen sit for 30 minutes before injecting the PLEGRIDY dose to allow the medication to reach room temperature. Do not use external heat sources such as hot water to warm the PLEGRIDY Pen. A room temperature solution is more comfortable to inject.

Supplies Needed for Your PLEGRIDY Injection:

1 PLEGRIDY Pen (See Figure A).

Before Use – Parts of your PLEGRIDY Pen (See Figure A):

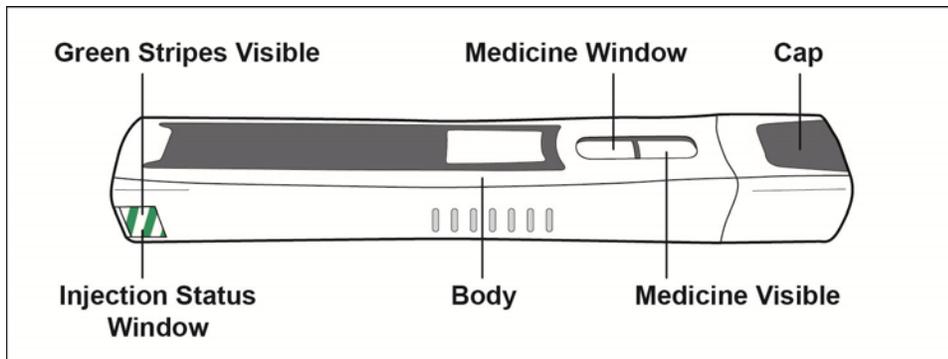


Figure A

⚠ Caution! Do not remove the cap until you are ready to inject. If you remove the cap, do not re-cap the pen. Re-capping could cause the pen to lock.

Additional supplies which are not included in the pack (See figure B): Alcohol wipe

- Gauze pad
- Adhesive bandage
- 1 sharps container for throwing away used PLEGRIDY pens. (See Disposing of Your Used PLEGRIDY pen at the end of these instructions).



Figure B

Preparing for your injection:

Step 1. Remove your pen from the refrigerator.

- a. Remove your PLEGRIDY pen from the refrigerator and select the appropriate pen (dosage) from the pack.
- b. Close the pack and put back in the refrigerator after removing one pen.
- c. **Let the PLEGRIDY pen come to room temperature for at least 30 minutes.**

⚠ Do not use external heat sources, such as hot water, to warm your pen

Step 2. Collect your supplies and wash your hands

- a. Find a well-lit area and a clean, flat surface to work on, like a table. Collect all the supplies you will need to give yourself, or to receive, an injection.
- b. Wash your hands with soap and water and dry thoroughly.

Step 3. Check your PLEGRIDY Pen (See Figure C)

- a. Check the injection status window.
You should see green stripes.
- b. Check the expiration date.
- c. Check the medication window and make sure the PLEGRIDY medicine is colourless.

Do not use your pen if:

- ⚠ You do not see the green stripes in the injection status window.
- It is past the expiration date.
- The liquid is cloudy or has floating particles in it.

Note: You might see air bubbles in the medication window. This is normal and will not affect your dose.

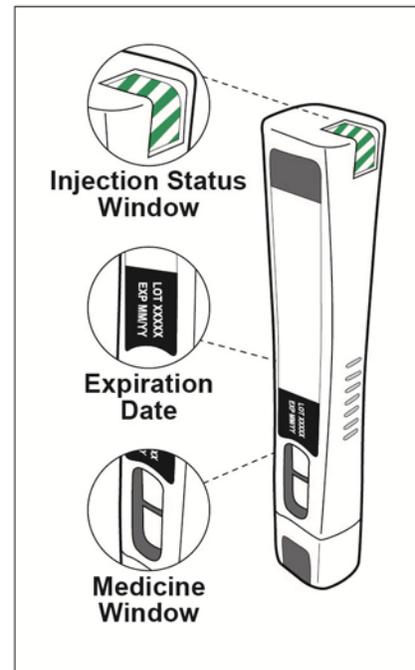


Figure C

Step 4. Choose and clean your injection site

- a. Choose an injection site in your thigh, abdomen, or the back of your upper arm (See Figure D).

⚠ **Do not** inject into an area of your body where the skin is irritated, red, bruised, tattooed, infected, or scarred.

- b. Wipe your skin with an alcohol wipe.

⚠ **Do not** touch or blow on this area again before giving your injection.

- c. Let your injection site dry on its own before injecting your dose.

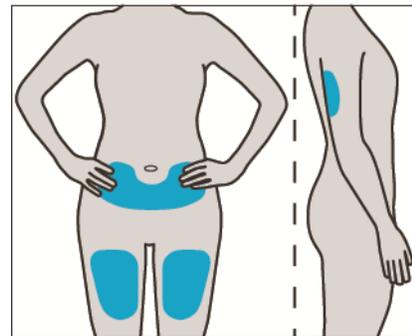


Figure D

Giving your injection:

Step 5. Remove the PLEGRIDY Pen cap

- a. Pull the pen cap straight off and set it aside for disposal after your injection (See *Figure E*). Your pen is ready to inject.

⚠ Warning! Do not touch, clean or manipulate the needle cover. You could get a needle stick or the pen may lock.

⚠ Caution! Do not recap your pen. This could lock the pen.

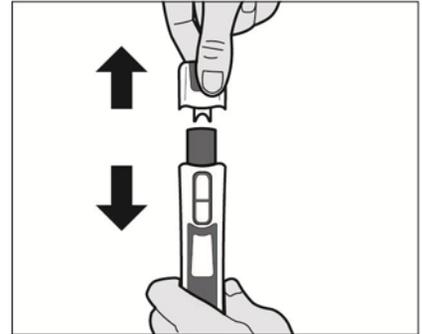


Figure E

Step 6. Give your injection

- a. Hold your pen over your chosen injection site. Make sure you can see the green stripes in the injection status window (See *Figure F*).

Note: Be ready to inject prior to pressing your pen down on your injection site, as the needle cover will lock when it is lifted from the site.

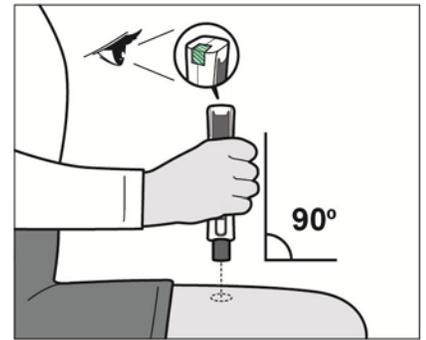


Figure F

- b. Firmly press and hold down your pen on your injection site until you hear the clicking sounds start (See *Figure G*).

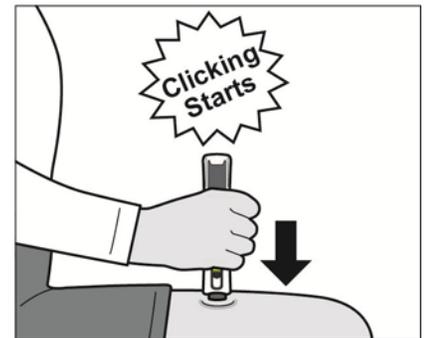


Figure G

- c. Continue to hold your pen firmly down on your injection site until the clicking sounds have stopped (see *Figure H*).

⚠ Do not lift your pen off your injection site until the clicking sounds stop and you see green checkmarks in the injection status window.

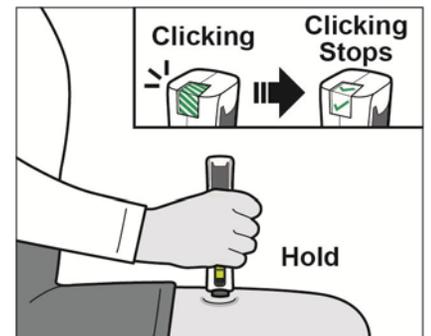


Figure H

If you do not hear clicking sounds and/or you do not see green checkmarks in the injection status window after attempting to inject, your pen may have locked and you should call the Biogen ONE® Support Program at 1-855-676-6300.

Step 7. Remove your PLEGRIDY Pen from your injection site

- a. After the clicking sound has stopped, lift your pen from your injection site. The needle cover will extend to cover the needle and will lock (See *Figure I*).

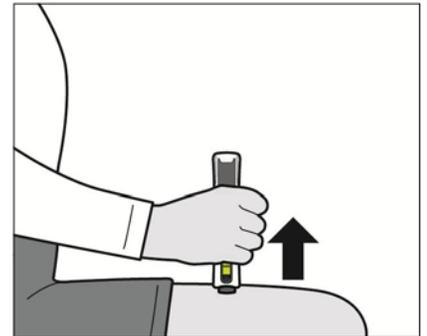


Figure I

Step 8. Check to make sure you have received your full dose of PLEGRIDY (see *Figure J*)

- a. Check the injection status window. You should see green checkmarks.
- b. Check the medication window. You should see a yellow plunger.

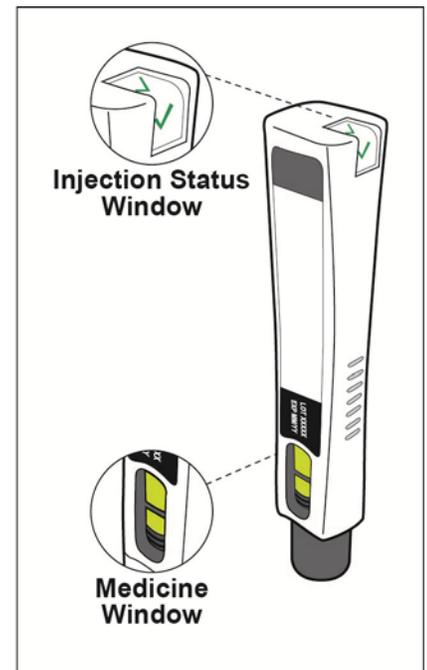


Figure J

After Your Injection

After Use – Parts of your PLEGRIDY Pen (see *Figure K*):

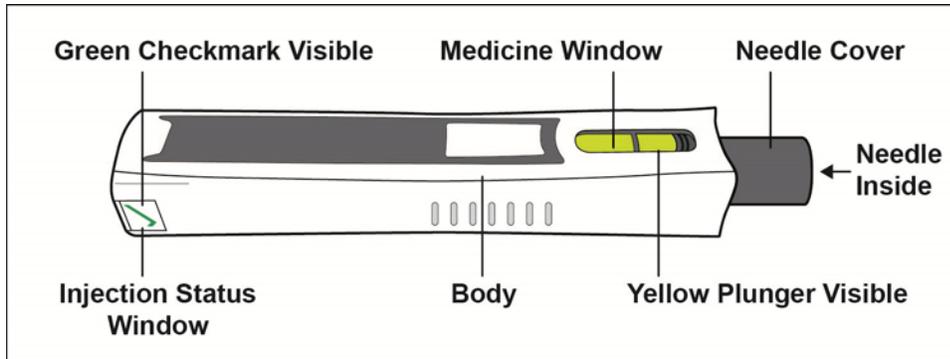


Figure K

Note: After the pen has been removed from the injection site, the needle cover will lock to protect against needle stick injury. **Do not** recap your pen.

After your injection:

Step 9. Dispose of your used PLEGRIDY Pens

- a. Throw away the used PLEGRIDY pens into a special secure container, such as a sharps bin, or according to community guidelines. Check with your doctor, pharmacist or nurse about the right way to throw away the container.

⚠ Do not dispose of your used pens or disposal container in your household trash unless your community guidelines permit this.

⚠ Do not recap your PLEGRIDY Pen.

Step 10. Care for injection site

- a. Apply a gauze pad or adhesive bandage to the injection site, if needed.

Step 11. Check your injection site

- a. Apply a gauze pad or adhesive bandage to the injection site, if needed.
- b. If you have a skin reaction and it does not clear up in a few days, contact your doctor or nurse.

Record Date and Location

- a) Record the date and location of each injection and alternate sites between your injections.
- b) Do not use the same injection site for consecutive injections.

Storage

- Recommended storage is controlled refrigeration 2°C to 8°C (36°F to 46°F) in the closed original carton to protect from light.
- If needed, PLEGRIDY may be stored in the closed original carton without refrigeration up to 25°C (up to 77°F) for up to 30 days.

 **Do not** freeze or expose to high temperatures.

If you want more information about PLEGRIDY:

- 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](#); the manufacturer's website www.biogen.ca, or by calling 1-866-477-3462.

This leaflet was prepared by Biogen Canada Inc.

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