#### **PLEGRIDY Instructions for Use**

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### INSTRUCTIONS FOR USE

#### PLEGRIDY® (PLEGG-rih-dee)

# (peginterferon beta-1a) injection, for Subcutaneous Use Single-Dose Prefilled Pen 125 mcg

**Important:** Do not remove the Plegridy Pen cap until you are ready to inject.

#### How to Inject your Plegridy Pen

Read this 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 healthcare provider about your medical condition or your treatment.

#### Note:

- Before you use your Plegridy Pen for the first time, your healthcare provider should show you or your caregiver how to prepare and inject your Plegridy Pen the right way.
- If you experience difficulty or have questions, call 1-800-456-2255.
- 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. By sharing the Pen, you may give an infection to them or get an infection from them.
- Take your Plegridy Pen out of the refrigerator and let it come to room temperature for at least 30 minutes before your injection.
- Do not use more than 1 Plegridy Pen every 14 days.
- Do not use your Plegridy Pen if it has been dropped or is visibly damaged.

#### How should I store Plegridy?

- Store Plegridy in the refrigerator between 36°F to 46°F (2°C to 8°C).
- If a refrigerator is not available, PLEGRIDY may be stored at room temperature up to 77°F (25°C) for up to 30 days in total.
- Keep Plegridy in the original carton to protect it from light.
- Do not freeze Plegridy.
- Keep Plegridy Pens, needles, and all medicines out of the reach of children.

#### **Supplies needed for your Plegridy Pen injection:**

• 1 Plegridy 125 mcg Pen (see Figure A)

#### Before Use – Parts of your Plegridy Pen (Figure A)

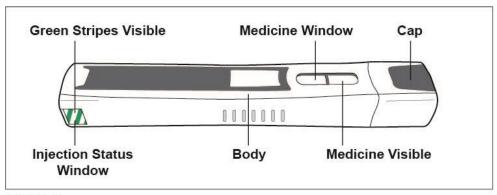


Figure A

Important: Do not remove the Plegridy Pen cap until you are ready to inject. If you remove the cap before you are ready to inject, 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 needles and Plegridy Pens. See "Disposing of your used Plegridy Pens" at the end of these instructions.
- a well-lit area and a clean, flat surface to work on, like a table

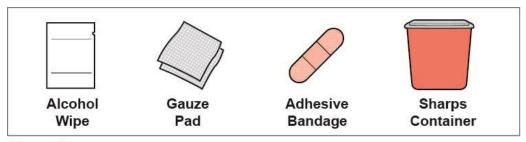


Figure B

#### Preparing for your injection:

## Step 1: Take your Plegridy Pen out of the refrigerator and let it come to room temperature for at least 30 minutes.

Do not use external heat sources such as hot water to warm your Plegridy Pen.

#### Step 2: Collect your supplies and wash your hands

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

Step 3: Check your Plegridy Pen (see Figure C)

- Check the injection status window on your Plegridy Pen. Before you give your injection, you should see green stripes in the injection status window.
  - Do not use Plegridy Pen if you do not see the green stripes in the injection status window.
- Check the expiration date printed on your Plegridy Pen.
  - Do not use Plegridy Pen past the expiration date.
- Check the medicine window on your Plegridy Pen and make sure the Plegridy medicine is clear and colorless.
  - Do not use Plegridy Pen if the liquid is colored, cloudy, or has floating particles in it.
  - You might see air bubbles in the medicine window. This is normal and will not affect your dose.

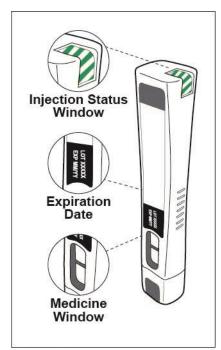


Figure C

#### Step 4: Choose and clean your injection site

- Plegridy Pen is for use under the skin only (subcutaneous).
- Plegridy Pen should be injected into 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, reddened, bruised, infected or scarred.

- Change (rotate) your injection site for each injection. Do not use the same injection site for each injection.
- Choose an injection site and wipe your skin with an alcohol wipe.
  - Do not touch this area again before giving your injection.
- Let your injection site dry on its own before injecting your dose.

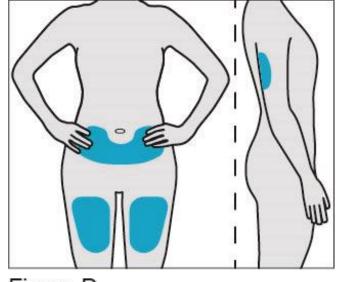
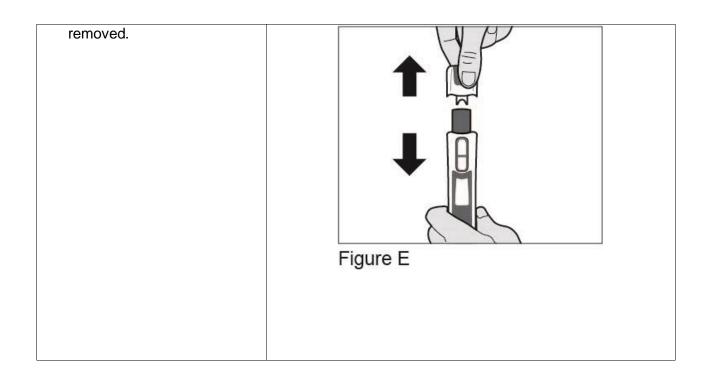


Figure D

#### Giving your injection:

#### Step 5: Remove the Plegridy Pen cap

- Pull the Plegridy Pen cap straight off and set it aside (See Figure E).
  - The needle is covered by the needle cover and the needle will not be seen.
- Important information:
  - Do not touch or clean the needle cover. You could get a needle stick injury or the pen may lock.
  - Do not recap your Plegridy Pen. This could lock the pen.
- Your Plegridy Pen is ready to inject after the cap is



#### Step 6: Give your injection

- Place your Plegridy Pen on your chosen injection site.
  - You should hold your Plegridy Pen at a 90° angle to your injection site so that you can see the green stripes in the injection status window (See Figure F).
  - Do not use your Plegridy Pen unless you see green stripes in the injection status window.

Note: Be ready to inject before you start pressing your Plegridy Pen down on your injection site. After you start pressing, the needle cover will lock when it is lifted from the site.

- Firmly press and hold down your Plegridy Pen on your injection site. This will insert the needle and start your injection (See Figure G).
  - You will hear a clicking sound.
- Continue to hold your Plegridy Pen firmly down on your injection site until the clicking sound has stopped (see Figure H).
  - Do not lift your Plegridy
     Pen off your injection site
     until the clicking sound
     stops and you see green
     checkmarks in the
     injection status window.

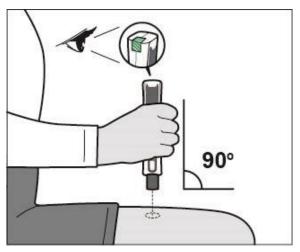


Figure F

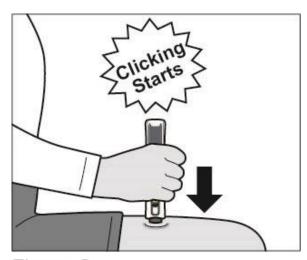
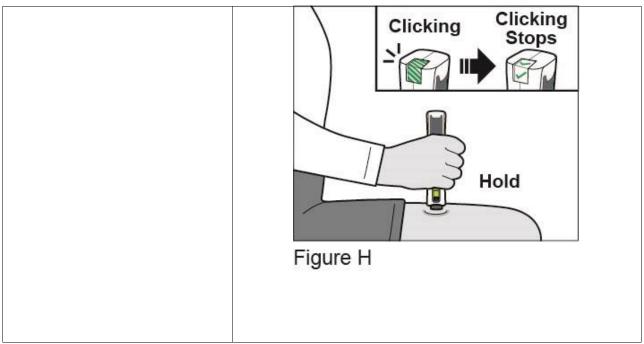


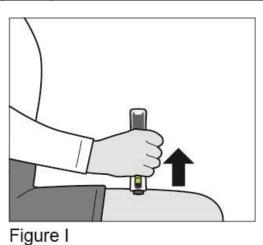
Figure G



If you do not hear clicking sounds or you do not see green checkmarks in the injection status window after trying to give your injection, your Plegridy Pen may have locked and you should call 1-800-456-2255.

Step 7: Remove your Plegridy Pen from your injection site

 After the clicking sound has stopped, lift your Plegridy Pen from your injection site. The needle will be covered and it will lock (see Figure I).



Step 8: Check and make sure you received your full dose of Plegridy (see Figure J)

- Check the injection status window. You should see green checkmarks in the injection status window.
- Check the medicine window. You should see a yellow plunger in the medicine window.
  - If you see blood at your injection site, wipe it off with gauze and apply an adhesive bandage.

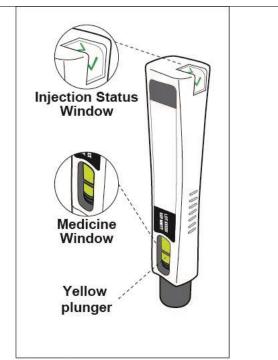


Figure J

#### After your injection:

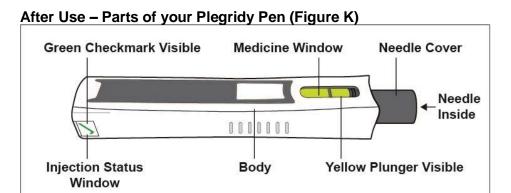


Figure K

Important: Do not touch the needle cover in any way. You could get a needle stick injury.

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 Plegridy Pen.

Step 9: Disposing of your used Plegridy Pens

- Put your used Plegridy Pens in an FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) Plegridy Pens in your household trash.
- If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:
  - o made of a heavy-duty plastic,
  - o can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out.
  - o upright and stable during use,
  - o leak resistant, and
  - o properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community
  guidelines for the right way to dispose of your sharps disposal container. There may be state
  or local laws about how you should throw away used needles and pens. For more
  information about safe sharps disposal, and for specific information about sharps disposal in
  the state that you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal.
- **Do not** dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. **Do not** recycle your used sharps disposal container.
- Do not recap your Plegridy Pen.

#### Step 10: Check your injection site

- Plegridy may commonly cause redness, pain or swelling of your skin at the injection site.
- After 2 hours, check your injection site for redness, swelling or tenderness. Call your healthcare provider right away if your injection site becomes swollen and painful or the area looks infected and does not heal within a few days.

#### Questions?

For product or service-related questions, call 1-800-456-2255 or go to <a href="https://www.plegridy.com">www.plegridy.com</a>.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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Issued: 03/2020

43644-03

# INSTRUCTIONS FOR USE PLEGRIDY® (PLEGG-rih-dee)

# (peginterferon beta-1a) injection, for Subcutaneous Use Single-Dose Prefilled Pen Starter Pack

**Important:** Do not remove the Plegridy Pen cap until you are ready to inject.

#### How to Inject your Plegridy Pen

Read this 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 healthcare provider about your medical condition or your treatment.

#### Note:

- Before you use your Plegridy Pen for the first time, your healthcare provider should show you or your caregiver how to prepare and inject your Plegridy Pen the right way.
- If you experience difficulty or have questions, call 1-800-456-2255.
- 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. By sharing the Pen, you may give an infection to them or get an infection from them.
- Take your Plegridy Pen out of the refrigerator and let it come to room temperature for at least 30 minutes before your injection.
- **Do not** use more than 1 Plegridy Pen every 14 days.
- **Do not** use your Plegridy Pen if it has been dropped or is visibly damaged.

#### How should I store Plegridy?

- Store Plegridy in the refrigerator between 36°F to 46°F (2°C to 8°C).
- If a refrigerator is not available, PLEGRIDY may be stored at room temperature up to 77°F (25°C) for up to 30 days in total.
- Keep Plegridy in the original carton to protect it from light.
- **Do not** freeze Plegridy.
- Keep Plegridy Pens, needles, and all medicines out of the reach of children.

#### Supplies needed for your Starter Pack for Plegridy Pen injection (See Figure A):

- 1 Starter Pack for Plegridy Pen which contains:
  - 1 Plegridy 63 mcg Pen (orange pen)
  - 1 Plegridy 94 mcg Pen (blue pen)



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 Pens. See "Disposing of your used Plegridy Pens" at the end of these instructions.
- a well-lit area and a clean, flat surface to work on, like a table

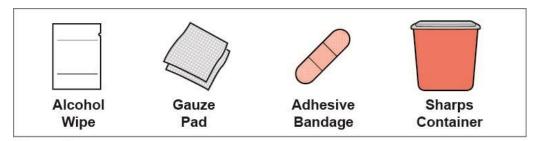


Figure B

#### **Dose Schedule**

• Choose the right Plegridy Pen for your dose. The Starter Pack for Plegridy Pen contains your first 2 injections to slowly adjust your dose.

When	Which Dose	Choose
Day 1	First Dose:	Orange Pen (See Figure C)
(63 mcg)	63 mcg	
		WA 1101010
		Figure C
When	Which Dose	Choose
Day 15	Second Dose:	Blue Pen (See Figure D)
(94 mcg)	94 mcg	



- Make sure you use the 63 mcg orange pen for your first dose (on day 1).
- Make sure you use the 94 mcg blue pen for your second dose (on day 15).

Ask your healthcare provider which Plegridy Pen you should use for your correct dose if you are not sure.

#### Before Use – Parts of your Plegridy Pen before use (See Figure E):

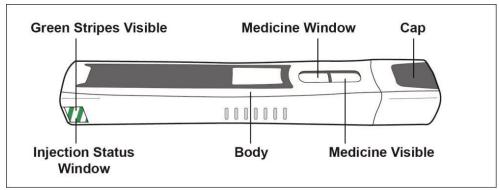


Figure E

Important: Do not remove the Plegridy Pen cap until you are ready to inject. If you remove the cap before you are ready to inject, do not re-cap the pen. Re-capping could cause the pen to lock.

#### Preparing for your injection:

Step 1: Take your Plegridy Pen out of the refrigerator and let it come to room temperature for at least 30 minutes.

Do not use external heat sources such as hot water to warm your Plegridy Pen.

#### Step 2: Collect your supplies and wash your hands

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

#### Step 3: Check your Plegridy Pen (see Figure F)

- Check the injection status window on your Plegridy Pen. Before you give your injection, you should see green stripes in the injection status window.
  - Do not use Plegridy Pen if you do not see the green stripes in the injection status window.
- Check the expiration date printed on your Plegridy Pen.
  - Do not use Plegridy Pen past the expiration date.
- Check the medicine window on your Plegridy Pen and make sure the Plegridy medicine is clear and colorless.
  - Do not use Plegridy Pen if the liquid is colored, cloudy, or has floating particles in it.
  - You might see air bubbles in the medicine window. This is normal and will not affect your dose.

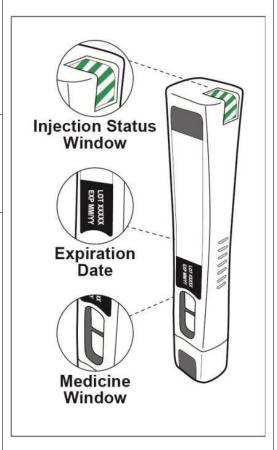


Figure F

#### Step 4: Choose and clean your injection site

- Plegridy Pen is for use under the skin only (subcutaneous).
- Plegridy Pen should be injected into your thigh, stomach area (abdomen) or the back of your upper arm (See Figure G).
  - Do not inject into an area of your body where the skin is irritated, reddened, bruised, infected or scarred.
- Change (rotate) your injection site for each injection. Do not use the same injection site for each injection.

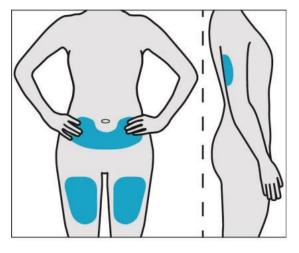


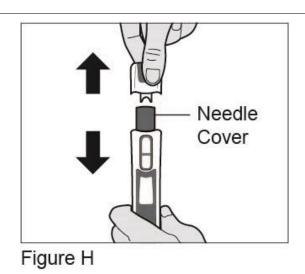
Figure G

- Choose an injection site and wipe your skin with an alcohol wipe.
  - Do not touch this area again before giving your injection.
- Let your injection site dry on its own before injecting your dose.

#### Giving your injection:

#### Step 5: Remove the Plegridy Pen cap

- Pull the Plegridy Pen cap straight off and set it aside (See Figure H).
  - The needle is covered by the needle cover and the needle will not be seen.
- Important information:
  - Do not touch or clean the needle cover. You could get a needle stick injury or the pen may lock.
  - Do not recap your Plegridy Pen. This could lock the pen.
- Your Plegridy Pen is ready to inject after the cap is removed.



#### Step 6: Give your injection

- Place your Plegridy Pen on your chosen injection site.
  - You should hold your Plegridy Pen at a 90° angle to your injection site so that you can see the green stripes in the injection status window (See Figure I).
  - Do not use your Plegridy Pen unless you see green stripes in the injection status window.

Note: Be ready to inject before you start pressing your Plegridy Pen down on your injection site. After you start pressing, the needle cover will lock when it is lifted from the site.

- Firmly press and hold down your Plegridy Pen on your injection site. This will insert the needle and start your injection (See Figure J).
  - You will hear a clicking sound.
- Continue to hold your Plegridy Pen firmly down on your injection site until the clicking sound has stopped (See figure K).
  - Do not lift your Plegridy Pen off your injection site until the clicking sound stops and you see green checkmarks in the injection status window.

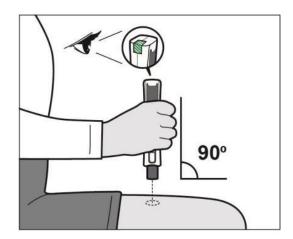


Figure I

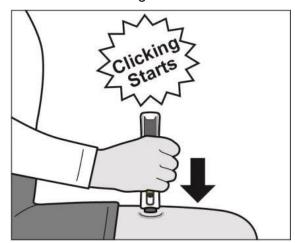


Figure J

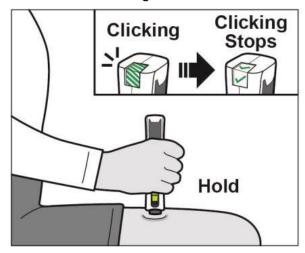


Figure K

If you do not hear clicking sounds, or you do not see green checkmarks in the injection status window after trying to give your injection, your Plegridy Pen may have locked and you should call 1-800-456-2255 for help.

Step 7: Remove your Plegridy Pen from your injection site

 After the clicking sound has stopped, lift your Plegridy Pen from your injection site. The needle will be covered by the needle cover and it will lock (see Figure L).

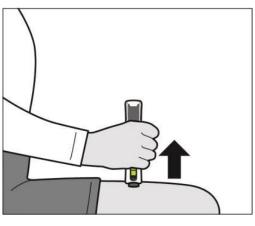


Figure L

#### Step 8: Check to make sure you have received your full dose of Plegridy (see Figure M)

- Check the injection status window. You should see green checkmarks in the injection status.
- Check the medicine window. You should see a yellow plunger in the medicine.
  - If you see blood at your injection site, wipe it off with the gauze pad and apply an adhesive bandage.

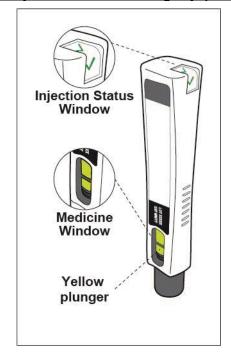


Figure M

#### After your injection:

After Use - Parts of your Plegridy Pen (Figure N)

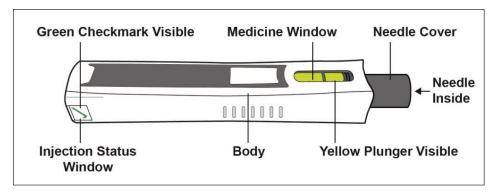


Figure N

**Important:** Do not touch the needle cover in any way. You could get a needle stick injury.

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 Plegridy Pen.

#### Step 9: Disposing of your used Plegridy Pens

- Put your used Plegridy Pens in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) Plegridy Pens in your household trash.**
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
  - o made of a 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,
  - o leak resistant, and
  - o properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community
  guidelines for the right way to dispose of your sharps disposal container. There may be state
  or local laws about how you should throw away used needles and pens. For more
  information about safe sharps disposal, and for specific information about sharps disposal in
  the state that you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal.
- **Do not** dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. **Do not** recycle your used sharps disposal container.
- Do not recap your Plegridy Pen.

#### Step 10: Check your injection site

- Plegridy may commonly cause redness, pain or swelling of your skin at the injection site.
- After 2 hours check your injection site for redness, swelling or tenderness.
- Call your healthcare provider right away if your injection site becomes swollen and painful or the area looks infected and does not heal within a few days.

#### Questions?

For product or service-related questions, call 1-800-456-2255 or go to www.plegridy.com.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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Issued: 03/2020

43839-03

#### INSTRUCTIONS FOR USE

#### PLEGRIDY® (PLEGG-rih-dee)

# (peginterferon beta-1a) injection, for Subcutaneous Use Single-Dose Prefilled Syringe 125 mcg

#### **How to Inject your Plegridy Prefilled Syringe**

Read this 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 healthcare provider about your medical condition or your treatment.

#### **Important Information**

Follow this Instructions for Use for the Plegridy prefilled syringe for subcutaneous use (under the skin). There is a different Instructions for Use for the Plegridy prefilled syringe for intramuscular use (into the muscle).

#### Note:

- Before you use your Plegridy Prefilled Syringe for the first time, your healthcare
  provider should show you or your caregiver how to prepare and inject your Plegridy Prefilled
  Syringe the right way.
- If you experience difficulty or have questions, call 1-800-456-2255.
- Plegridy Prefilled Syringe is for use under the skin only (subcutaneous).
- Each Plegridy Prefilled Syringe can be used 1 time only. Do not share your Plegridy Prefilled Syringe with anyone else. By sharing the needle, you may give an infection to them or get an infection from them.
- Take your Plegridy Prefilled Syringe out of the refrigerator and let it come to room temperature for at least 30 minutes before your injection.
- Do not use more than 1 Plegridy Prefilled Syringe every 14 days.
- **Do not** use your Plegridy Prefilled Syringe if it has been dropped or is visibly damaged.

#### How should I store Plegridy?

- Store Plegridy in the refrigerator between 36°F to 46°F (2°C to 8°C).
- If a refrigerator is not available, PLEGRIDY may be stored at room temperature up to 77°F (25°C) for up to 30 days in total.
- Keep Plegridy in the original carton to protect it from light.
- Do not freeze Plegridy.

 Keep Plegridy Prefilled Syringes, needles, and all medicines out of the reach of children.

#### Supplies needed for your Plegridy Prefilled Syringe injection:

1 Plegridy 125 mcg Prefilled Syringe (See Figure A)

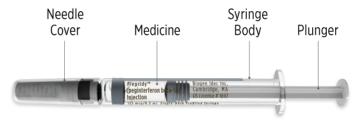


Figure A

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 Prefilled Syringes. See "Disposing of your used Plegridy Prefilled Syringes" at the end of these instructions.
- a well-lit area and a clean, flat surface to work on, like a table



Figure B

#### Preparing for your injection:

## Step 1: Take your Plegridy Prefilled Syringe out of the refrigerator and let it come to room temperature for at least 30 minutes.

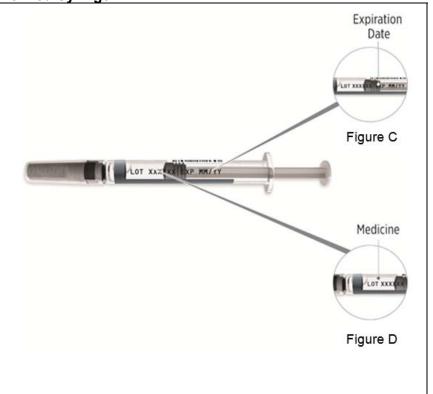
 Do not use external heat sources such as hot water to warm your Plegridy Prefilled Syringe.

#### Step 2: Collect your supplies and wash your hands

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

Step 3: Check your Plegridy Prefilled Syringe

- Check the expiration date printed on your Plegridy Prefilled Syringe (See Figure C).
  - Do not use Plegridy Prefilled Syringe past the expiration date.
- Check that your Plegridy medicine is clear and colorless (See Figure D).
  - Do not use Plegridy Prefilled Syringe if the liquid is colored, cloudy, or has floating particles in it.
  - You might see air bubbles in your Plegridy medicine. This is normal and will not affect your dose.



Step 4: Choose and clean your injection site

- Plegridy Prefilled Syringe is for use under the skin only (subcutaneous).
- Plegridy Prefilled Syringe should be injected into your thigh, abdomen or the back of your upper arm (See Figure E).
  - Do not inject directly into your belly button.
  - Do not inject into an area of your body where the skin is irritated, reddened, bruised, infected or scarred.
- Change (rotate) your injection site for each injection. Do not use the same injection site for each injection.
- Choose an injection site and wipe your skin with an alcohol wipe.
  - Do not touch this area again before giving your injection.
- Let your injection site dry on its own before injecting your dose.
- Do not take off the Plegridy Prefilled Syringe needle cover until you are ready to inject.

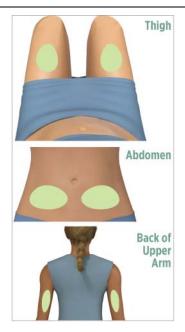


Figure E

#### **Giving Your Injection:**

Step 5: Remove the Plegridy Prefilled Syringe needle cover

- With 1 hand, hold your Plegridy Prefilled Syringe. With your other hand, firmly hold the needle cover and pull the needle cover straight off the needle (See Figure F).
  - Be careful when removing the needle cover to avoid getting a needle stick injury.
  - Do not touch the needle.
  - Important: Do not recap the Plegridy Prefilled Syringe. You could get a needle stick injury.
  - Throw away the needle cover after your injection.

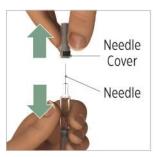


Figure F

Step 6: Gently pinch the injection site

 With 1 hand, use your thumb and first finger and pinch the skin around your cleaned injection site (See Figure G).



Figure G

**Step 7: Give your Plegridy Prefilled Syringe injection** 

- With your other hand, hold your Plegridy
   Prefilled Syringe like a pencil. Use a quick dartlike motion and insert the needle at a 90° angle into your skin (See Figure H).
- After the needle is in, let go of your skin.

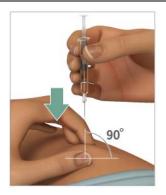


Figure H

- Slowly push the plunger down until the syringe is empty (See Figure I).
  - Do not take your Plegridy Prefilled Syringe out of your injection site until you have slowly pushed the plunger all the way down.



Figure I

- Pull the needle straight out of your skin (See Figure J).
  - If you see blood at your injection site, wipe it off with gauze and apply an adhesive bandage.
- Important: Do not recap your Plegridy Prefilled Syringe. You could get a needle stick injury.
- **Do not** reuse your Plegridy Prefilled Syringe.

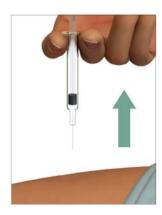


Figure J

#### **After Your Injection:**

#### Step 8: Disposing of your used Plegridy Prefilled Syringes

- Put your used Plegridy Prefilled Syringes in an FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) Plegridy Prefilled Syringes in your household trash.
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
  - o made of a heavy-duty plastic,
  - o can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
  - o upright and stable during use,
  - o leak resistant, and
  - o properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community
  guidelines for the right way to dispose of your sharps disposal container. There may be state
  or local laws about how you should throw away used needles and syringes. For more
  information about safe sharps disposal, and for specific information about sharps disposal in
  the state that you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal.
- **Do not** dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. **Do not** recycle your used sharps disposal container.

#### Step 9: Check your injection site

- Plegridy may commonly cause redness, pain or swelling of your skin at the injection site.
- After 2 hours, check your injection site for redness, swelling or tenderness.
- Call your healthcare provider right away if your injection site becomes swollen and painful or the area looks infected and does not heal within a few days.

#### Questions?

For product or service-related questions, call 1-800-456-2255 or go to www.plegridy.com.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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Issued: 1/2021 43654-04

#### INSTRUCTIONS FOR USE

#### PLEGRIDY® (PLEGG-rih-dee)

# (peginterferon beta-1a) injection for Subcutaneous Use Single-Dose Prefilled Syringe Starter Pack

#### How to Inject your Plegridy Prefilled Syringe

Read this 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 healthcare provider about your medical condition or your treatment.

#### Note:

- Before you use your Plegridy Prefilled Syringe for the first time, your healthcare provider should show you or your caregiver how to prepare and inject your Plegridy Prefilled Syringe the right way.
- If you experience difficulty or have questions, call 1-800-456-2255.
- Plegridy Prefilled Syringe is for use under the skin only (subcutaneous).
- Each Plegridy Prefilled Syringe can be used 1 time only. Do not share your Plegridy Prefilled Syringe with anyone else. By sharing the needle, you may give an infection to them or get an infection from them.
- Take your Plegridy Prefilled Syringe out of the refrigerator and let it come to room temperature for at least 30 minutes before your injection.
- Do not use more than 1 Plegridy Prefilled Syringe every 14 days.
- **Do not** use your Plegridy Prefilled Syringe if it has been dropped or is visibly damaged.

#### How should I store Plegridy?

- Store Plegridy in the refrigerator between 36°F to 46°F (2°C to 8°C).
- If a refrigerator is not available, PLEGRIDY may be stored at room temperature up to 77°F (25°C) for up to 30 days in total.
- Keep Plegridy in the original carton to protect it from light.
- Do not freeze Plegridy.
- Keep Plegridy Prefilled Syringes, needles, and all medicines out of the reach of children.

## Supplies needed for your Starter Pack for Plegridy Prefilled Syringe injection (See Figure A):

- 1 Starter Pack for Plegridy Prefilled Syringe which contains:
  - 1 Plegridy 63 mcg Prefilled Syringe (orange syringe)

o 1 Plegridy 94 mcg Prefilled Syringe (blue syringe)



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 Prefilled Syringes. See "Disposing of your used Plegridy Prefilled Syringes" at the end of these instructions.
- a well-lit area and a clean, flat surface to work on, like a table



Figure B

#### **Dose Schedule**

 Choose the right Plegridy Prefilled Syringe for your dose. The Starter Pack for Plegridy Prefilled Syringe contains your first 2 injections to slowly adjust your dose.

When	Which Dose	Choose
Day 1	First Dose:	Orange Syringe (See Figure C)
(63 mcg)	63 mcg	Too Many Sept
		Figure C
When	Which Dose	Choose
Day 15	Second Dose:	Blue Syringe (See Figure D)
(94 mcg)	94 mcg	Took I 154 see, Day 15)
		Figure D

- Make sure you use the 63 mcg orange syringe for your first dose (on day 1).
- Make sure you use the 94 mcg blue syringe for your second dose (on day 15).

Ask your healthcare provider which Plegridy Prefilled Syringe you should use for your correct dose if you are not sure.

#### Parts of your Plegridy Prefilled Syringe (See Figure E):

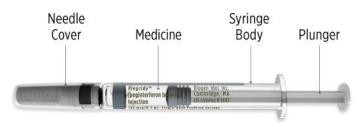


Figure E

#### Preparing for your injection:

Step 1: Take your Plegridy Prefilled Syringe out of the refrigerator and let it come to room temperature for at least 30 minutes.

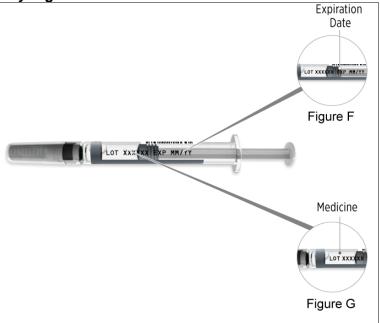
 Do not use external heat sources such as hot water to warm your Plegridy Prefilled Syringe.

#### Step 2: Collect your supplies and wash your hands

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

Step 3: Check your Plegridy Prefilled Syringe

- Check the expiration date printed on your Plegridy Prefilled Syringe (See Figure F).
  - Do not use Plegridy Prefilled Syringe past the expiration date.
- Check that your Plegridy medicine is clear and colorless (See Figure G).
  - Do not use Plegridy Prefilled Syringe if the liquid is colored, cloudy, or has floating particles in it.
  - You might see air bubbles in your Plegridy medicine. This is normal and will not affect your dose.



Step 4: Choose and clean your injection site

- Plegridy Prefilled Syringe is for use under the skin only (subcutaneous).
- Plegridy Prefilled Syringe should be injected into your thigh, stomach area (abdomen) or the back of your upper arm (See Figure H).
  - Do not inject directly into your belly button.
  - Do not inject into an area of your body where the skin is irritated, reddened, bruised, infected or scarred.
- Change (rotate) your injection site for each injection. Do not use the same injection site for each injection.
- Choose an injection site and wipe your skin with an alcohol wipe.
  - Do not touch this area again before giving your injection.
- Let your injection site dry on its own before injecting the dose.
- Do not take off the Plegridy Prefilled Syringe needle cover until you are ready



Figure H

to inject.

#### **Giving Your Injection:**

Step 5: Remove the Plegridy Prefilled Syringe needle cover

- With 1 hand, hold your Plegridy Prefilled Syringe. With your other hand, firmly hold the needle cover and pull the needle cover straight off the needle (See Figure I).
  - Be careful when removing the needle cover to avoid getting a needle stick injury.
  - o **Do not** touch the needle.
  - Important: Do not recap the Plegridy Prefilled Syringe. You could get a needle stick injury.
  - Throw away the needle cover after your injection.

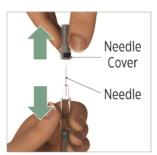


Figure I

#### Step 6: Gently pinch the injection site

 With 1 hand, use your thumb and first finger and pinch the skin around your cleaned injection site (See Figure J).



Figure J

#### **Step 7: Give your Plegridy Prefilled Syringe injection**

- With your other hand, hold your Plegridy Prefilled Syringe like a pencil. Use a quick dart-like motion and insert the needle at a 90° angle into your skin (See Figure K).
- After the needle is in, let go of your skin.

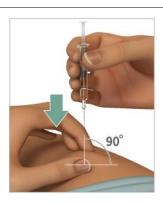


Figure K

- Slowly push the plunger down until the syringe is empty (See Figure L).
  - Do not take your Plegridy Prefilled Syringe out of your injection site until you have slowly pushed the plunger all the way down.

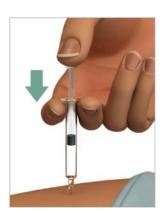


Figure L

- Pull the needle straight out of your skin (See Figure M).
  - If you see blood at your injection site, wipe it off with the gauze pad and apply an adhesive bandage.
- Important: Do not recap your Plegridy Prefilled Syringe. You could get a needle stick injury.
- **Do not** reuse your Plegridy Prefilled Syringe.

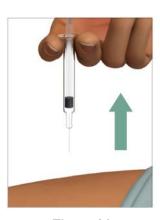


Figure M

#### After Your Injection:

#### **Step 8: Disposing of your used Plegridy Prefilled Syringes**

- Put your used Plegridy Prefilled Syringes in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) Plegridy Prefilled Syringes in your household trash.
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
  - o made of a heavy-duty plastic,
  - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
  - o upright and stable during use,
  - o leak resistant, and
  - o properly labeled to warn of hazardous waste inside the container.

- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal.
- **Do not** dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. **Do not** recycle your used sharps disposal container.

#### Step 9: Check your injection site

- Plegridy may commonly cause redness, pain or swelling of your skin at the injection site.
- After 2 hours check your injection site for redness, swelling or tenderness.
- Call your healthcare provider right away if your injection site becomes swollen and painful or the area looks infected and does not heal within a few days.

#### **Questions?**

For product or service-related questions, call 1-800-456-2255 or go to www.plegridy.com.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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Issued: 03/2020

43840-03

### Instructions for Use

PLEGRIDY® (PLEGG-rih-dee)

(peginterferon beta-1a)

#### injection for intramuscular use

Single-Dose Prefilled Syringe

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

#### Important information:

- The tip of the cap of the Plegridy prefilled syringe is made of natural rubber latex. Tell your healthcare provider if you are allergic to rubber or latex.
- Follow this Instructions for Use for the Plegridy prefilled syringe for intramuscular use (into the muscle). There is a different Instructions for Use for the Plegridy prefilled syringe for subcutaneous use (under the skin).

#### Note:

- Before you use your Plegridy prefilled syringe for the first time, your healthcare provider should show you or your caregiver how to prepare and inject your Plegridy prefilled syringe the right way.
- Each Plegridy prefilled syringe can be used 1 time only. Do not share your Plegridy prefilled syringe with anyone else. By sharing the needle, you may give an infection to them or get an infection from them.
- Do not use more than 1 Plegridy prefilled syringe every 14 days.

#### How should I store Plegridy?

- Store Plegridy in the refrigerator between 36°F to 46°F (2°C to 8°C).
- If a refrigerator is not available, Plegridy may be stored at room temperature up to 77°F (25°C) for a total of 30 days.
- You can store your Plegridy prefilled syringes at room temperature and then put it back in the refrigerator.
- **Do not** freeze Plegridy. **Do not** use Plegridy that has been frozen.
- Store Plegridy in the original carton to protect it from light.

Keep the Plegridy prefilled syringe and all medicines out of the reach of children.

#### Supplies you will need for the Plegridy injection:

- 1 Plegridy Administration Dose Pack that contains:
  - 1 Plegridy prefilled syringe
  - o 23 gauge, 11/4 inch long sterile needle



#### Additional supplies not included in your Plegridy Administration Dose pack:

- 1 alcohol wipe
- 1 gauze pad
- 1 adhesive bandage

a sharps disposal container for throwing away used syringes and needles. See "After the Plegridy injection" at the
end of these instructions.



#### Preparing the dose of Plegridy:

- Find a well-lit, clean, flat work surface like a table and collect all the supplies you will need to give yourself or receive an injection.
- Take 1 Plegridy Administration Dose Pack out of the refrigerator and let it come to room temperature for about 30 minutes. **Do not** use external heat sources such as hot water to warm the Plegridy prefilled syringe.
- Check the expiration date printed on the Plegridy prefilled syringe, Plegridy Administration Dose Pack, and the outer carton. **Do not** use the Plegridy prefilled syringe past the expiration date.
- Wash your hands with soap and water.

#### Identifying parts of the Plegridy prefilled syringe (See Figure A).

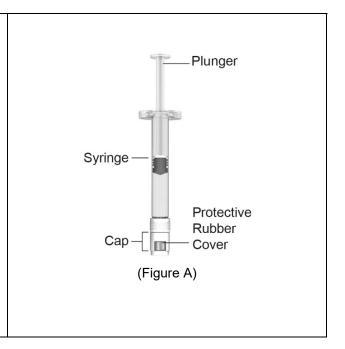
#### Preparing the Plegridy injection:

### **Step 1:** Check the Plegridy prefilled syringe (See Figure A):

- The syringe should not have any cracks or damage.
- Check that the cap is intact and has not been removed.
- Plegridy should look slightly clear, colorless to slightly yellow, and should not have any particles in it.

Do not use the Plegridy prefilled syringe if:

- the syringe is cracked or damaged.
- the solution is cloudy, colored other than slightly yellow, or has lumps or particles in it.
- the cap has been removed or is not tightly attached.



If you cannot use that syringe, you will need to get a new syringe. Contact Biogen at 1-800-456-2255.

**Step 2:** With 1 hand, hold the Plegridy prefilled syringe right under the cap and with the cap pointing up (See Figure B).

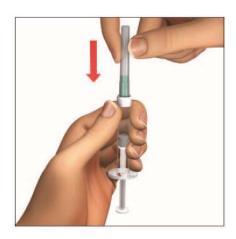
 Make sure you are holding the Plegridy prefilled syringe by the ridged part, directly under the cap.



(Figure B)

**Step 3:** With the other hand, grasp the cap and bend it at a 90° angle until the cap snaps off (See Figure C and Figure D). (Figure C) glass syringe tip (Figure D)

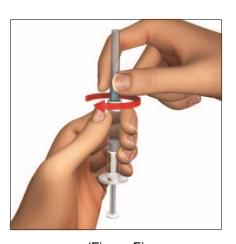
**Step 4:** Open the sterile needle package and take out the covered needle. Hold the Plegridy prefilled syringe with the glass syringe tip pointing up. Press the needle on the Plegridy prefilled syringe glass tip (See Figure E).



(Figure E)

**Step 5:** Gently turn the needle to the right (clockwise) until it is tight and firmly attached (See Figure F).

- If the needle is not firmly attached, it may leak and you may not get your full dose of Plegridy.
- Do not remove the protective cover from the needle.



(Figure F)

#### Giving the Plegridy injection:

- Your healthcare provider should show you or a caregiver how to prepare and inject the dose of Plegridy before the
  Plegridy prefilled syringe is used for the first time. Your healthcare provider should watch you inject the dose of
  Plegridy the first time the Plegridy prefilled syringe is used.
- Inject your Plegridy exactly as your healthcare provider has shown you.
- Plegridy is injected into the muscle (intramuscularly).
- Plegridy should be injected into the thigh (See Figure G).
- Change (rotate) your injection sites for each dose. **Do not** use the same injection site for each injection.
- **Do not** inject into an area of the body where the skin is irritated, reddened, bruised, infected or scarred in any way.

<ul> <li>Step 6: Choose your left or right thigh and wipe the skin with an alcohol wipe (See Figure G). Let the injection site dry before injecting the dose.</li> <li>Do not touch this area again before giving the injection.</li> </ul>	(Figure G)		
Step 7: Pull the protective cover straight off the needle (See Figure H). Do not twist the cover off.			
	(Figure H)		
<b>Step 8:</b> With 1 hand, stretch the skin out around the injection site. With the other hand, hold the syringe like a pencil. Use a quick dart-like motion and insert the needle at a 90° angle, through the skin and into the muscle (See Figure I). After the needle is in, let go of the skin.	90°		
	(Figure I)		
Step 9: Slowly push the plunger down until the syringe is empty (See Figure J).	Plunger (Figure J)		
<ul> <li>Step 10: Pull the needle out of the skin (See Figure K). Press down on the injection site with the gauze pad for a few seconds or rub gently in a circular motion.</li> <li>If you see blood after you press the injection site for a few seconds, wipe it off with the gauze pad and apply an adhesive bandage.</li> </ul>	90°		
	(Figure K)		

## After the Plegridy injection:

- **Do not** recap the needle. Recapping the needle can lead to a needle stick injury.
- Put your used needles and syringes in a FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) loose needles and syringes in your household trash.
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:

- o made of heavy-duty plastic,
- o can be closed with a tight-fitting puncture-resistant lid, without sharps being able to come out,
- o upright and stable during use,
- o leak-resistant, and
- o properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way
  to dispose of your sharps disposal container. There may be state or local laws about how you should throw away
  used needles and syringes. For more information about safe sharps disposal, and for specific information about
  sharps disposal in the state that you live in, go to the FDA's website at: <a href="http://www.fda.gov/safesharpsdisposal">http://www.fda.gov/safesharpsdisposal</a>
- Do not dispose of your used sharps disposal container in your household trash unless your community guidelines
  permit this. Do not recycle your used sharps disposal container.

## **Check your injection site:**

• After 2 hours, check the injection site for redness, pain, itching, swelling, tenderness, a break in your skin that becomes blue and black, or drains fluid. If you have a skin reaction and it does not clear up in a few days, contact your healthcare provider.

#### General information about the safe and effective use of Plegridy

- Always use a new Plegridy prefilled syringe and needle for each injection. Do not re-use your Plegridy prefilled syringe or needles.
- Do not share your Plegridy prefilled syringe or needles.

Manufactured by:

Biogen Inc.

Cambridge, MA, 02142, USA

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1-800-456-2255

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Issued: 1/2021

54927-01

#### Instructions for Use

## PLEGRIDY® (PLEGG-rih-dee)

(peginterferon beta-1a)

#### injection for intramuscular use

#### Titration Kit for use with the PLEGRIDY intramuscular Single-Dose Prefilled Syringe Only

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

**Important information:** The tip of the cap of the Plegridy prefilled syringe is made of natural rubber latex. Tell your healthcare provider if you are allergic to rubber or latex.

#### Note:

- Before you use your Plegridy prefilled syringe for the first time, your healthcare provider should show you or your caregiver how to prepare and inject your Plegridy prefilled syringe the right way.
- Each Plegridy prefilled syringe can be used 1 time only. Do not share your Plegridy prefilled syringe with anyone else. By sharing the needle, you may give an infection to them or get an infection from them.
- Do not use more than 1 Plegridy prefilled syringe every 14 days.

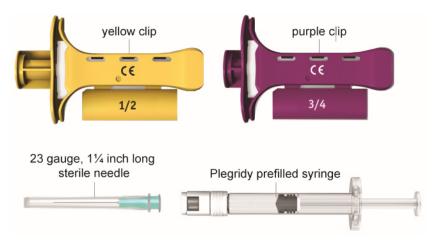
#### How should I store Plegridy?

- Store Plegridy in the refrigerator between 36°F to 46°F (2°C to 8°C).
- If a refrigerator is not available, Plegridy may be stored at room temperature up to 77°F (25°C) for a total of 30 days.
  - o You can store your Plegridy prefilled syringes at room temperature and then put it back in the refrigerator.
- **Do not** freeze Plegridy. **Do not** use Plegridy that has been frozen.
- Store Plegridy in the original carton to protect it from light.

Keep the Plegridy Titration Kit, the Plegridy prefilled syringe, and all medicines out of the reach of children.

## Supplies you will need for the Plegridy injection:

- 1 Plegridy Titration Kit that contains:
  - 1 yellow clip
  - o 1 purple clip
- 1 Plegridy Administration Dose Pack that contains:
  - 1 Plegridy prefilled syringe
  - o 23 gauge, 11/4 inch long sterile needle



#### Additional supplies not included in your Plegridy Titration Kit and Plegridy Administration Dose Pack:

- 1 alcohol wipe
- 1 gauze pad
- 1 adhesive bandage
- a sharps disposal container for throwing away used syringes and needles. See "After the Plegridy injection" at the end of these instructions.



### **Preparing the Plegridy Prefilled Syringe:**

- Find a well-lit, clean, flat work surface like a table and collect all the supplies youwill need to give yourself or receive an injection.
- Take 1 Plegridy Administration Dose Pack out of the refrigerator and let it come to room temperature for about 30 minutes. Do not use external heat sources such as hot water to warm the Plegridy prefilled syringe.
- Check the expiration date printed on the Plegridy prefilled syringe, Plegridy prefilled syringe Administration Dose Package carton, and the outer carton. **Do not** use the Plegridy prefilled syringe past the expiration date.
- Wash your hands with soap and water.

## Identifying parts of the Plegridy prefilled syringe (See Figure A).

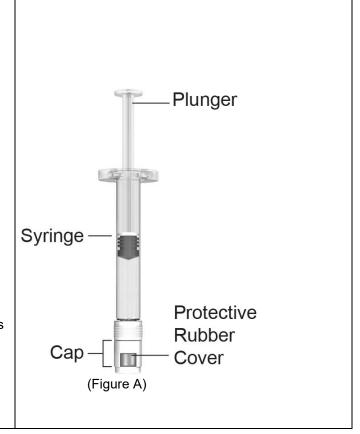
## **Preparing the Plegridy injection:**

# **Step 1:** Check the Plegridy prefilled syringe (Figure A):

- The syringe should not have any cracks or damage.
- Check that the cap is intact and has not been removed.
- Plegridy should look slightly clear, colorless to slightly yellow, and should not have any particles in it.
- **Do not** use the Plegridy prefilled syringe if:
  - the syringe is cracked or damaged.
  - the solution is cloudy, colored other than slightly yellow, or has lumps or particles in it.
  - the cap has been removed or is not tightly attached.

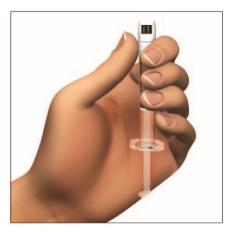
If you cannot use that syringe, you will need to get a new

syringe. Contact Biogen at 1-800-456-2255.



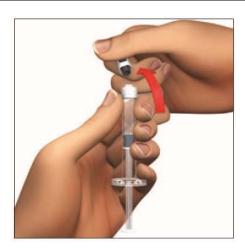
Step 2: With 1 hand, hold the Plegridy prefilled syringe right under the cap and with the cap pointing up (See Figure B).

 Make sure you are holding the Plegridy prefilled syringe by the ridged part, directly under the cap.

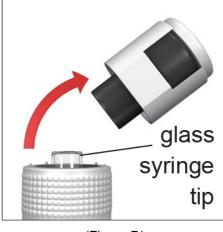


(Figure B)

**Step 3:** With the other hand, grasp the cap and bend it at a 90° angle until the cap snaps off (See Figure C and Figure D).

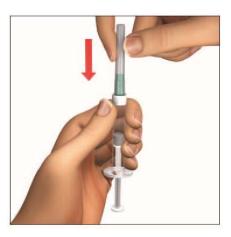


(Figure C)



(Figure D)

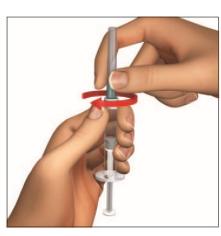
**Step 4:** Open the sterile needle package and take out the covered needle. Hold the Plegridy prefilled syringe with the glass syringe tip pointing up. Press the needle on the Plegridy prefilled syringe glass tip (See Figure E).



(Figure E)

**Step 5:** Gently turn the needle to the right (clockwise) until it is tight and firmly attached (See Figure F).

- If the needle is not firmly attached, it may leak and you may not get your full dose of Plegridy.
- Do not remove the protective cover from the needle.

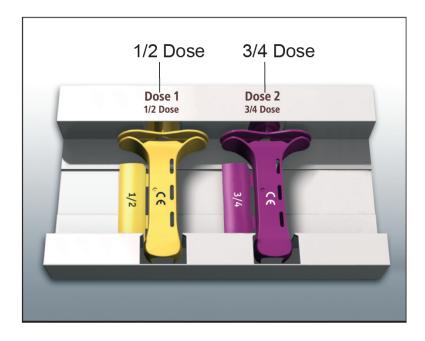


(Figure F)

## Using the Plegridy prefilled syringe with the Plegridy Titration Kit:

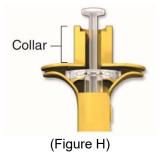
- You must prepare the Plegridy prefilled syringe and needle before you put it into the Plegridy titration clip. Follow Step 1 to Step 5 above to prepare the Plegridy prefilled syringe.
- Your Plegridy dose may be titrated over 2 doses by using the Plegridy prefilled syringe with the Plegridy Titration Kit.
  - Oose 1 (Day 1): ½ dose (yellow clip)
  - O Dose 2 (Day 15): 3/4 dose (purple clip)
  - O Dose 3 (Day 29): a full dose (no clip needed)
- The 2 Plegridy titration clips are for single-use only with the Plegridy prefilled syringe. Do not
  re-use the Plegridy prefilled syringe or Plegridy titration clips.

# Identifying the parts of Plegridy Titration Kit (See Figure G):

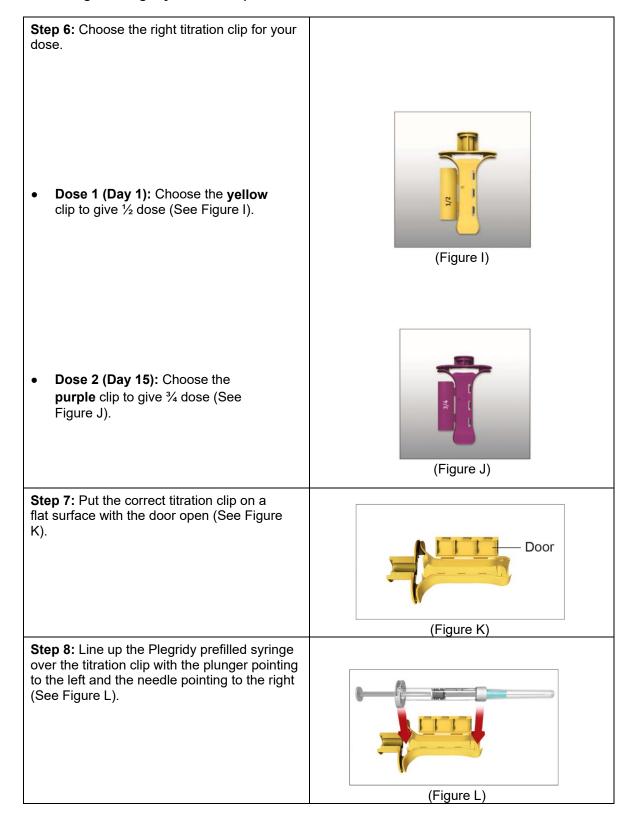


(Figure G)

• The Plegridy titration clip has a "collar" on top that will stop the syringe from injecting a full dose (See Figure H). The "collar" is to make sure that you receive the correct dose.



## Attaching the Plegridy titration clip:



Step 9: Push the Plegridy prefilled syringe down into the titration clip until both ends "snap" into place (See Figure M).	(Figure M)
<ul> <li>Step 10: Using 2 fingers, push the door down until it closes over the Plegridy prefilled syringe (See Figure N).</li> <li>You will hear a "snap" when the door is closed the right way. Do not open door after it is closed.</li> </ul>	(Figure N)
Step 11: Check to make sure that the Plegridy prefilled syringe is in the titration clip the right way and that the door is tightly closed.	(Figure O)

# Giving the Plegridy injection:

- Your healthcare provider should show you or a caregiver how to prepare and inject the dose
  of Plegridy before the Plegridy prefilled syringe is used for the first time. Your healthcare
  provider should watch you inject the dose of Plegridy the first time the Plegridy prefilled
  syringe is used.
- Inject your Plegridy exactly as your healthcare provider has shown you.
- Plegridy is injected into the muscle (intramuscularly).
- Plegridy should be injected into the thigh (See Figure P).
- Change (rotate) your injection sites for each dose. Do not use the same injection site for each injection.
- **Do not** inject into an area of the body where the skin is irritated, reddened, bruised, infected or scarred in any way.

<ul> <li>Step 12: Choose your left or right thigh and wipe the skin with an alcohol wipe (See Figure P). Let the injection site dry before injecting the dose.</li> <li>Do not touch this area again before giving the injection.</li> </ul>	(Figure P)
Step 13: Pull the protective cover straight off the needle (See Figure Q). Do not twist the cover off.	(Figure Q)
<b>Step 14:</b> With 1 hand, stretch the skin out around the injection site. With the other hand, hold the syringe like a pencil. Use a quick dart-like motion and insert the needle at a 90° angle, through the skin and into the muscle (See Figure R). After the needle is in, let go of the skin.	(Figure R)
Step 15: Slowly push the plunger all the way down until it touches the collar (See Figure S).	(Figure S)
<ul> <li>Step 16: Pull the needle out of the skin (See Figure T). Press down on the injection site with the gauze pad for a few seconds or rub gently in a circular motion.</li> <li>If you see blood after you press the injection site for a few seconds, wipe it off with the gauze pad and apply an adhesive bandage.</li> </ul>	(Figure T)

#### After the Plegridy injection:

- Do not recap the needle. Recapping the needle can lead to a needle stick injury.
- Put your used needles and syringes in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and syringes in your household trash.
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
  - o made of heavy-duty plastic,
  - o can be closed with a tight-fitting puncture-resistant lid, without sharps being able to come out,
  - o upright and stable during use,
  - o leak-resistant, and
  - o properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community
  guidelines for the right way to dispose of your sharps disposal container. There may be state or
  local laws about how you should throw away used needles and syringes. For more information
  about safe sharps disposal, and for specific information about sharps disposal in the state that you
  live in, go to the FDA's website at: <a href="http://www.fda.gov/safesharpsdisposal">http://www.fda.gov/safesharpsdisposal</a>
- **Do not** dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

#### Check the injection site:

After 2 hours, check the injection site for redness, pain, itching, swelling, tenderness, a break
in your skin that becomes blue and black, or drains fluid. If you have a skin reaction and it
does not clear up in a few days, contact your healthcare provider.

#### General information about the safe and effective use of Plegridy

- Always use a new Plegridy prefilled syringe, titration clip, and needle. **Do not** re-use your Plegridy prefilled syringe, titration clip, or needle.
- **Do not** share your Plegridy prefilled syringe, titration clip, or needle.
- You can use the table below to keep track of your injections.

Day	Dose	Use Titration Clip	Date/Time
Day 1	1/2 Dose	Yellow	
Day 15	3/4 Dose	Purple	
Day 29	Full Dose	None	

Manufactured for:

Biogen Inc.

Cambridge, MA 02142 USA

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1-800-456-2255

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Revised: 1/2021

54930-01