Package leaflet: Information for the user

Plegridy 63 micrograms solution for injection in pre-filled pen
Plegridy 94 micrograms solution for injection in pre-filled pen
Plegridy 125 micrograms solution for injection in pre-filled pen
peginterferon beta-1a

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. **What Plegridy is and what it is used for**
2. **What you need to know before you use Plegridy**
3. **How to use Plegridy**
4. **Possible side effects**
5. **How to store Plegridy**
6. **Contents of the pack and other information**
7. **Instructions for injecting Plegridy pre-filled pen**

1. What Plegridy is and what it is used for

What Plegridy is
The active substance in Plegridy is peginterferon beta-1a. Peginterferon beta-1a is a modified long-acting form of interferon. Interferons are natural substances made in the body to help protect from infections and diseases.

What Plegridy is used for
This medicine is used to treat relapsing-remitting multiple sclerosis (MS) in adults aged 18 or over.
MS is a long term illness that affects the central nervous system (CNS), including the brain and spinal cord, in which the body's immune system (its natural defences) damages the protective layer (myelin) that surrounds the nerves in the brain and spinal cord. This disrupts the messages between the brain and other parts of the body, causing the symptoms of MS. Patients with relapsing-remitting MS have periods when the disease is not active (remission) in between flare-ups of symptoms (relapses).

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 thinking and concentrating, depression.

How Plegridy works
Plegridy seems to work by stopping the body's immune system from damaging 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.

2. What you need to know before you use Plegridy

Do not use Plegridy
- **If you are allergic** to peginterferon beta-1a, interferon beta-1a or any of the ingredients of this medicine (listed in section 6). See section 4 for the symptoms of an allergic reaction.
- **If you have severe depression** or think about committing suicide.

Warnings and precautions
Talk to your doctor if you have ever had:
- **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 mood in the past.

Talk to your doctor, pharmacist or nurse before injecting Plegridy **if you have any of the conditions listed below.** They may get worse while using Plegridy**:**
- **Serious liver or kidney problems**
- **Irritation at an injection site,** which can lead to skin and tissue damage (*injection site necrosis*). When you are ready to inject, carefully follow the instructions in section 7 "*Instructions for injecting Plegridy pre-filled pen*", at the end of this leaflet. This is to reduce the risk of injection site reactions.
- **Epilepsy** or other seizure disorders, not controlled by medicine
- **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 (*arrhythmia*).
- **Thyroid problems**
- **A low number of white blood cells or platelets**, which can cause an increased risk of infection, or bleeding

Other things to consider when using Plegridy
- You will need blood tests to determine your numbers of blood cells, blood chemistry and your levels of liver enzymes. These will be performed before you start using Plegridy, regularly after treatment with Plegridy has been initiated and then periodically during treatment, even if you have no particular symptoms. These blood tests will be in addition to the tests which are normally done to monitor your MS.
- The functioning of your thyroid gland will be checked regularly or whenever thought necessary by your doctor for other reasons.
- Blood clots in the small blood vessels may occur during your treatment. These blood clots could affect your kidneys. This might happen several weeks to several years after starting Plegridy. Your doctor may want to check your blood pressure, blood (platelet count) and the function of your kidneys.

If you accidentally prick yourself or someone else with the needle in Plegridy, the area affected should be washed **immediately** with soap and water and a **doctor or nurse should be contacted as soon as possible.**

Children and adolescents
Plegridy should **not be used** in children and adolescents because it is yet to be established whether it would work for them and whether it would be safe.

Other medicines and Plegridy
Plegridy should be used carefully with medicines that are broken down in the body by a group of proteins called "cytochrome P450" (e.g. some medicines used for epilepsy or depression).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially those used to treat epilepsy or depression. This includes any medicines obtained without a prescription.

Sometimes you will need to remind other healthcare professionals 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 breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

No harmful effects on the breastfed newborn/infant are anticipated. Plegridy can be used during breast-feeding.

Driving and using machines
Plegridy has no or negligible influence on the ability to drive and use machines.

Plegridy contains sodium
This medicine contains less than 1 mmol sodium (23 mg), that is to say it is essentially "sodium-free".

3. How to use Plegridy

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose
One injection of Plegridy 125 micrograms every 14 days (every two weeks). 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 effects of Plegridy before taking the full dose. You will be provided with an Initiation Pack containing your first 2 injections: one orange pen with Plegridy 63 micrograms (for day 0) and one blue pen with Plegridy 94 micrograms (for day 14).

After that you will be provided with a maintenance pack containing grey pens with Plegridy 125 micrograms (for day 28 and then every two weeks).

Read the instructions in section 7 "*Instructions for injecting Plegridy pre-filled pen*" at the end of this leaflet before you start using Plegridy.
Use the record table printed on the inside of the lid of the Initiation Pack to keep a track of your injection dates.

Injecting yourself
Plegridy is to be injected under the skin (*subcutaneous injection*). Alternate the sites you use for injections. Do not use the same injection site for consecutive injections.
You can inject Plegridy yourself without the help of your doctor, if you have been trained how to do this.

- Read and follow the advice given in the instructions in section 7 "*Instructions for injecting Plegridy pre-filled pen*" before you start.
- **If you have trouble** handling the pen, ask your doctor or nurse who may be able to help.

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.

If you use more Plegridy than you should
You must only inject Plegridy once 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 forget to use Plegridy
You need to inject Plegridy once 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, do not inject more than once in a 7-day period. Do not use two injections to make up for a missed injection.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects
- **Liver problems**

(common - may affect up to 1 in 10 people)
If you get any of these symptoms:
- Yellowing of your skin or the whites of your eyes
- Itching all over
- Feeling sick, being sick *(nausea and vomiting)*
- Easy bruising of the skin
    - **Contact a doctor immediately.** They may be signs of a possible liver problem.

- **Depression**

(common - may affect up to 1 in 10 people)
If you:
- Feel unusually sad, anxious or worthless or
- Have thoughts about suicide
    - **Contact a doctor immediately.**

- **Serious allergic reaction**

(uncommon - may affect up to 1 in 100 people)
If you get any of these:
- Difficulty breathing
- Swelling around the face (lips, tongue or throat)
- Skin rashes or redness
    - **Contact a doctor immediately.**

- **Seizures**

(uncommon - may affect up to 1 in 100 people)
If you have a seizure or a fit
    - **Contact a doctor immediately.**

- **Injection site damage**

(rare - may affect up to 1 in 1,000 people)
If you get any of these symptoms:
- Any break in the skin together with swelling, inflammation or fluid leaking around the injection site
    - **Contact a doctor for advice.**

- **Kidney problems including scarring that may reduce your kidney function**

(rare - may affect up to 1 in 1,000 people)
If you get some or all of these symptoms:
- Foamy urine
- Fatigue
- Swelling, particularly in the ankles and eyelids, and weight gain.
    - **Contact a doctor as they may be signs of a possible kidney problem.**

- **Blood problems**

(rare - may affect up to 1 in 1,000 people)
The following may occur: Blood clots in the small blood vessels that can affect your kidneys (thrombotic thrombocytopenic purpura or haemolytic uremic syndrome). Symptoms may include increased bruising, bleeding, fever, extreme weakness, headache, dizziness or light-headedness. Your doctor may find changes in your blood and the function of your kidneys.

If you get some or all of these symptoms:
- Increased bruising or bleeding
- Extreme weakness
- Headache, dizziness or light-headedness
    - **Contact a doctor immediately.**

Other side effects
Very common side effects

(may affect more than 1 in 10 people)

- Flu-like symptoms. These symptoms are not really flu, see below. You can't pass it on to anyone else.
- Headache
- Muscle pain (*myalgia*)
- Pain in your joints, arms, legs or neck (*arthralgia*)
- Chills
- Fever
- Feeling weak and tired (*asthenia*)
- Redness, itching or pain around the place you have injected
    - **If any of these effects trouble you, contact a doctor.**

Flu-like symptoms

Flu-like symptoms are more common when you first start using Plegridy. They gradually get less as you keep using your injections. See below for simple ways to manage these flu-like symptoms if you get them.

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. On average, flu-like symptoms begin approximately 10 hours after injection and last between 12 and 24 hours.
2. Take paracetamol or ibuprofen half an hour before your Plegridy injection and continue to take paracetamol or ibuprofen for the duration of your flu-like symptoms. 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.

Common side effects

(may affect up to 1 in 10 people)

- Feeling or being sick *(nausea or vomiting)*
- Hair loss (*alopecia*)
- Itchy skin (*pruritus*)
- Increase in body temperature
- Changes around the place you have injected such as swelling, inflammation, bruising, warmth, rash or colour change
- Changes in your blood which might cause tiredness or reduced ability to fight infection
- Increases in liver enzymes in the blood (will show up in blood tests)
    - **If any of these effects trouble you, talk to your doctor.**

Uncommon side effects

(may affect up to 1 in 100 people)

- Hives
- Changes in your blood which might cause unexplained bruising or bleeding.
    - **If any of these effects trouble you, talk to your doctor.**

Frequency not known

(frequency cannot be estimated from the available data)

- Pulmonary arterial hypertension: A disease of severe narrowing of the blood vessels in the lungs resulting in high blood pressure in the blood vessels that carry blood from the heart to the lungs. Pulmonary arterial hypertension has been seen at various time points during treatment, including several years after starting treatment with interferon beta-products.

Children (10 years of age and above) and adolescents
In clinical trials, some side effects were reported very commonly in both adults and children, e.g., redness at the injection site, flu-like symptoms, headache, and fever.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme.
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

In order to improve the traceability of this medicine, your doctor or pharmacist should record the name and the lot number of the product you have been given in your patient file. You may also wish to make a note of these details in case you are asked for this information in the future.

5. How to store Plegridy

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

Do not use this medicine after the expiry date which is stated on the carton and the label after "EXP". The expiry date refers to the last day of that month.

- Store in the original package in order to protect from light. Only open the pack when you need a new pen.

- **Store in a refrigerator** (fridge), 2º-8ºC.
  - Do not freeze. Throw away any Plegridy that is accidentally frozen.

- Plegridy can be kept outside a fridge at room temperature (up to 25°C) for up to 30 days but it must be kept **away from light**.
  - Packs can be taken out of the fridge and then put back in a fridge more than once if you need to.
  - Make sure the time the pens spend out of a fridge is **no more than 30 days in total**.
  - Throw away any pen that is kept out of the fridge for more than 30 days.
  - If you are unsure of the number of days you have kept a pen out of the fridge, throw the pen away.

- Do not use this medicine if you notice any of the following:
  - If the pen is broken.
  - If the solution is coloured, cloudy or you can see particles floating in it.

- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Plegridy contains
The active ingredient is peginterferon beta-1a.

Each 63 microgram pre-filled pen contains 63 micrograms of peginterferon beta-1a in 0.5 mL solution for injection.
Each 94 microgram pre-filled pen contains 94 micrograms of peginterferon beta-1a in 0.5 mL solution for injection.
Each 125 microgram pre-filled pen contains 125 micrograms of peginterferon beta-1a in 0.5 mL solution for injection.

The other ingredients are: Sodium acetate trihydrate, acetic acid glacial, arginine hydrochloride, polysorbate 20 and water for injections (see Section 2 “Plegridy contains Sodium”).

What Plegridy looks like and contents of the pack
Plegridy is a clear and colourless solution for injection in a glass pre-filled pen with an attached needle.

Pack sizes:
- The Plegridy Initiation Pack contains one orange pre-filled pen of 63 micrograms and one blue pre-filled pen of 94 micrograms.
- The 125 micrograms grey pens are provided in a pack containing either two or six pre-filled pens.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Biogen Netherlands B.V.
Prins Mauritslaan 13
1171 LP Badhoevedorp
The Netherlands

Manufacturer
FUJIFILM Diosynth Biotechnologies Denmark ApS
Biotek Allé 1
DK-3400 Hillerød
Denmark

Biogen Netherlands B.V.
Prins Mauritslaan 13
1171 LP Badhoevedorp
The Netherlands

This leaflet was last revised in January 2026

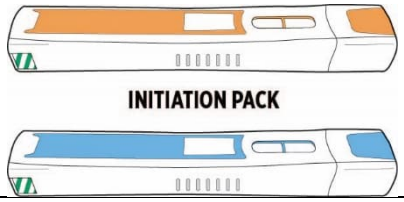
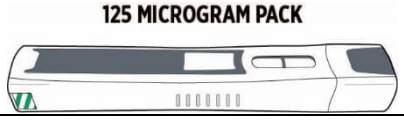
7. Instructions for injecting Plegridy pre-filled pen

⚠ **Caution! Do not** remove the cap until you are ready to inject.

How to Inject Plegridy
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 pen for the first time**, your doctor or nurse should show you or your carer how to prepare and inject the pen.
- The pen is for use under the skin only (subcutaneous).
- Each pen can be used once only.
- ⚠ **Do not share** the 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 the pen if it has been **dropped or is visibly damaged.**

Dosage schedule
The Initiation Pack contains your first two injections to gradually adjust your dose. Choose the correct pen from a pack.

When	Which dose	Which pack
Day 0 (63 micrograms)	First injection: 63 micrograms, choose orange pen	
Day 14 (94 micrograms)	Second injection: 94 micrograms, choose blue pen	
Day 28 and then every two weeks after that (125 micrograms)	Full dose injection: 125 micrograms, choose grey pen	

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

Supplies needed for your Plegridy Pen injection:
- 1 Plegridy Pen (see Figure A)

Before use – Parts of Plegridy Pen (Figure A)

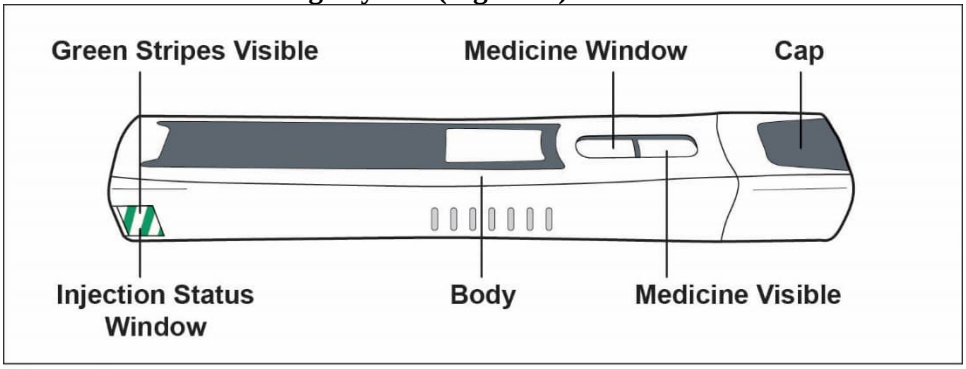


Figure A

⚠ **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):

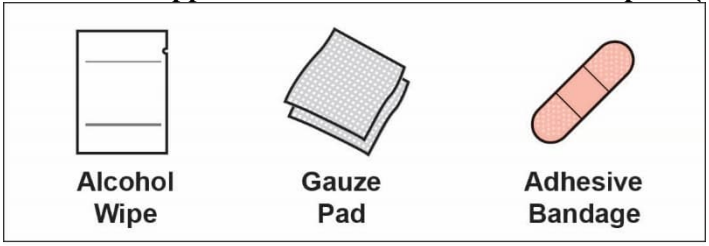


Figure B

Preparing for your injection

Step 1: Remove your pen from the fridge.

a. Remove your Plegridy pack from the fridge and select the appropriate pen (dosage) from the pack.
b. Close the pack and put back in the fridge after removing one pen.
c. **Let the pen warm 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, clean, flat surface to work on like a table. Collect all the supplies you will need to give yourself, or receive, an injection.
b. Wash your hands with soap and water.

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

a. Check the injection status window. You should see green stripes.

b. Check the expiry date.

c. Check the medicine window and make sure the Plegridy medicine is clear and colourless.

⚠ **Do not** use the pen if:

- **You do not see the green stripes** in the injection status window.
- **It is expired.**
- **The liquid is coloured, cloudy or contains floating particles.**

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

⚠ **Do not use** the pen if it has been **dropped or is visibly damaged.**

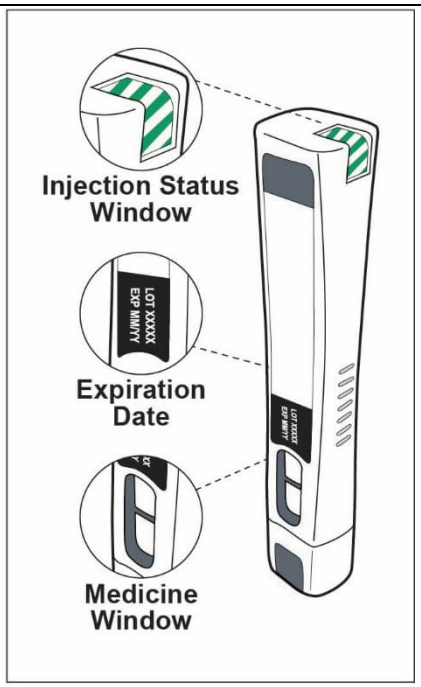


Figure C

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 highlighted areas in Figure D).

- If some areas are too difficult for you to reach, ask a carer who has been trained to help you.

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

⚠ **Do not** inject directly **into your belly button.**

b. Wipe your skin with an alcohol wipe.

⚠ **Note: 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.

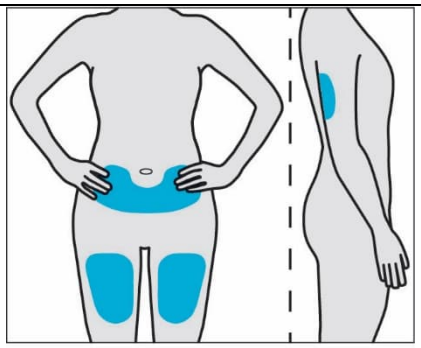


Figure D

Giving your injection

Step 5: Remove the Plegridy pen cap

a. Pull the pen cap straight off and set it aside (see Figure E). Your pen is now ready to inject.

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

⚠ **Caution! Do not** re-cap your pen. This could lock the pen

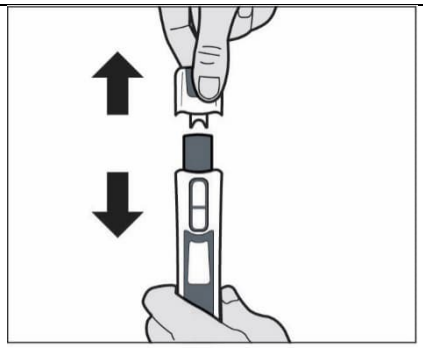


Figure E

Step 6: Give the injection

a. Hold the pen over your injection site. Make sure you can see the green stripes in the injection status window (see Figure F).
   - You should hold the pen over your injection site at 90º angle.

   ⚠ **Warning!** Do not rest the pen on the injection site until you are ready to inject. This may cause the pen to accidently lock.

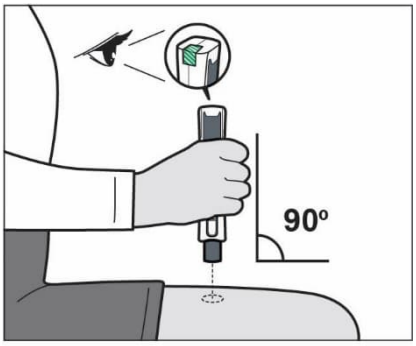


Figure F

b. Firmly press and hold down the pen on your injection site. You will hear the clicking sounds start. This tells you that the injection is happening (see Figure G).

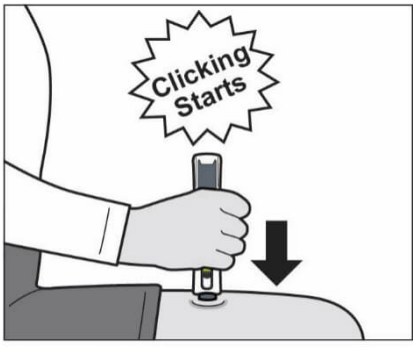


Figure G

c. Continue to hold the 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 ticks in the injection status window.
- **Warning! If you do not hear clicking sounds or you do not see green ticks** in the injection status window after attempting to inject, the pen may have locked and you may not have received your injection. You should then **contact your doctor, nurse or pharmacist.**

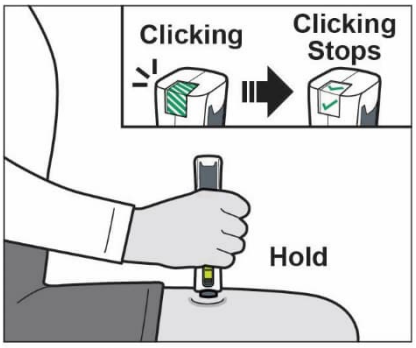


Figure H

Step 7: Remove the Plegridy pen from your injection site

a. After the clicking sound has stopped, lift the pen from your injection site. The needle cover will extend to cover the needle and will lock (see Figure I).
   - If you see blood at your injection site, wipe it off with the gauze pad and apply an adhesive bandage or plaster

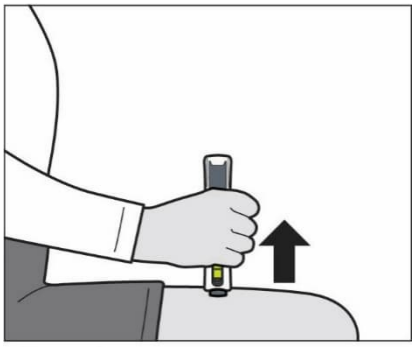
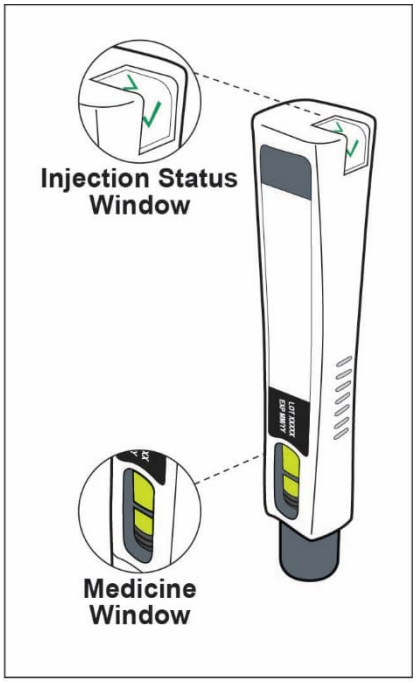


Figure I

Step 8: Check to make sure you received your full dose of Plegridy (see Figure J)	
a. Check the injection status window. You should see green ticks. b. Check the medicine window. You should see a yellow plunger.	 *Figure J*

After the injection
After Use – Parts of your Plegridy pen (see Figure K):

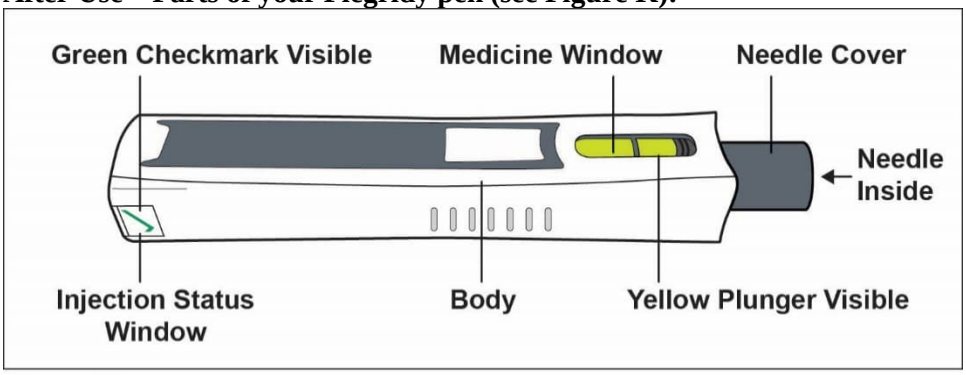


Figure K

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

Step 9: Dispose of used Plegridy pen

- Check with your doctor, pharmacist or nurse about the right way to throw away the used pen.
- **Do not re-cap the pen.**

Step 10: Care for your injection site

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

Step 11: Check injection site

- After 2 hours, check the injection 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.

Record date and location

- Record the date and location of each injection.
- For the Initiation Pack injections, you can use the record table printed on the inside of the lid of the Initiation Pack.

General warnings

- ⚠ Do not reuse your Plegridy pen.
- ⚠ Do not share your Plegridy pen.
- **Keep Plegridy pen and all medicines out of reach of children.**

Storage

- Recommended storage is controlled refrigeration 2°C to 8°C 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 for up to 30 days.
- **Plegridy can be removed from and returned to the refrigerator if necessary. The total combined time out of refrigeration at a temperature up to 25°C, should not exceed 30 days.**
- ⚠ **Do not** freeze or expose to high temperatures.