

Instructions for Use
Palynziq (Pal-lin-zeek)
(pegvaliase-pqpz)
Injection for Subcutaneous Use
Single-Dose Prefilled Syringe

Read this Instructions for Use before you start using the Palynziq prefilled syringe and each time you get a new 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.

Follow these instructions carefully while you are using Palynziq. If your healthcare provider decides that you (or your caregiver) can give the injections of Palynziq at home, your healthcare provider will show you (or your caregiver) how to inject Palynziq the right way. Your healthcare provider should watch you (or your caregiver) give the first Palynziq injection and monitor you for signs and symptoms of a severe allergic reaction (anaphylaxis). **Do not** inject Palynziq until your healthcare provider shows you (or your caregiver) how to inject Palynziq the right way and has watched you (or your caregiver) give your injection.

Talk to your healthcare provider if you (or your caregiver) have any questions about how to inject Palynziq the right way.

Do not share your prefilled syringes with anyone else. You may give an infection to them or get an infection from them.

Store your Palynziq prefilled syringe(s) in its original carton in the refrigerator. See “Storage of Palynziq” at the end of this Instructions for Use.

Supplies you will need for each injection of Palynziq (See Figure A):

- Palynziq prefilled syringe(s) in sealed tray(s). **Each tray contains 1 prefilled syringe. You may need more than 1 prefilled syringe for your prescribed dose.**
- 1 gauze pad or cotton ball
- 1 alcohol pad
- 1 bandage
- 1 puncture resistant or sharps disposal container. See “Dispose of the used prefilled syringes” at the end of this Instructions for Use.

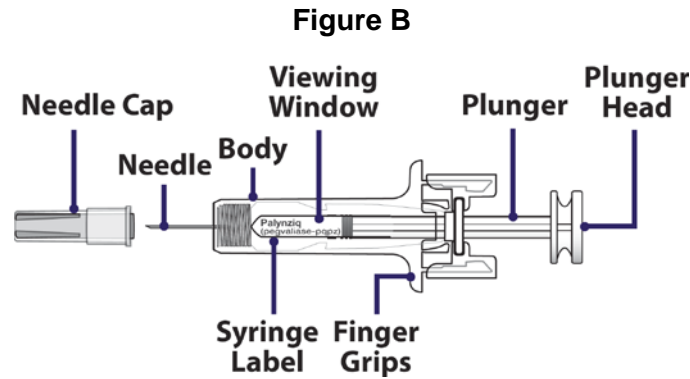
Figure A



Important things to know about using your Palynziq prefilled syringe:

- Inject only 1 time with each Palynziq prefilled syringe. **Do not** use a Palynziq syringe more than 1 time.
- **Do not** pull back on the plunger at any time.
- **Do not** remove the needle cap until you are ready to inject.

Figure B below shows what the prefilled syringe looks like before use.



Select the correct Palynziq prefilled syringe(s) for your dose. You may need more than 1 prefilled syringe for your prescribed dose. Your healthcare provider will tell you which syringe(s) to use. Ask your healthcare provider if you have any questions.

When you receive your Palynziq prefilled syringe(s), check that the name “Palynziq” appears on the carton(s).

- Palynziq prefilled syringes come in 3 different strengths (See Figure C).
- Before you inject Palynziq, check each carton and syringe to make sure you have the right prefilled syringe for your prescribed dose.

Figure C



Set up your injection

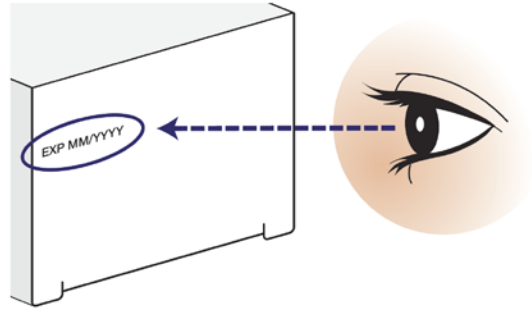
Step 1: Gather your supplies for the injection(s) (See Figure A) and place them on a clean flat surface.

Take out the number of cartons needed for your prescribed dose from the refrigerator.

Check the expiration date (EXP) on the carton(s) (See Figure D).

- If the expiration date has passed, **do not** use the prefilled syringe(s) in that carton. Call BioMarin at 1-866-906-6100 or your healthcare provider for help with Palynziq.

Figure D



Step 2: Open the carton(s) and take out the sealed tray(s) that you need for your prescribed dose (See Figure E). You may need more than 1 prefilled syringe for your prescribed dose.

Place the sealed tray(s) on a clean, flat surface out of reach of children and pets.

Put the carton with any remaining trays back in the refrigerator.

Figure E



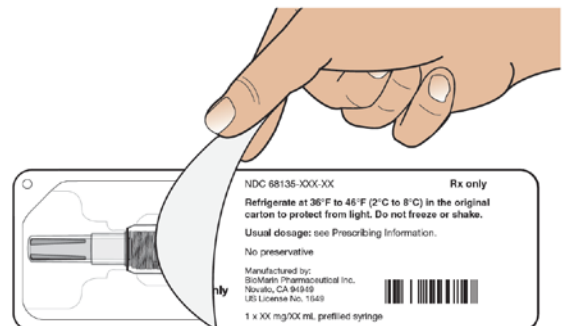
Step 3: Let the sealed tray(s) sit at room temperature for **at least 30 minutes**. Injecting Palynziq when cold can make the injection feel uncomfortable.

- **Do not** warm up the prefilled syringe in any other way other than letting it sit at room temperature. **Do not** warm in a microwave and **do not** place in hot water.

Let the sealed tray(s) sit at room temperature for at least 30 minutes before opening.

Step 4: Peel off the cover from the tray (See Figure F).

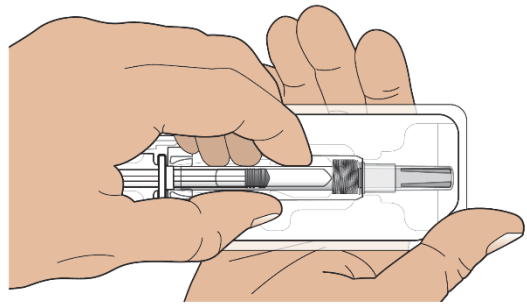
Figure F



Step 5: Hold the middle of the prefilled syringe body and remove the prefilled syringe from the tray (See Figure G).

- **Throw away** the prefilled syringe if it looks damaged or used, and use a new prefilled syringe for your injection. See “**Dispose of the used prefilled syringes**” at the end of this Instructions for Use. Call BioMarin at 1-866-906-6100 or your healthcare provider for help with Palynziq.
- **Do not** remove the needle cap from the prefilled syringe until Step 12.
- **Do not** shake or roll the syringe in your hands.

Figure G



Step 6: Check the prefilled syringe label to make sure you have the correct strength for your prescribed dose.

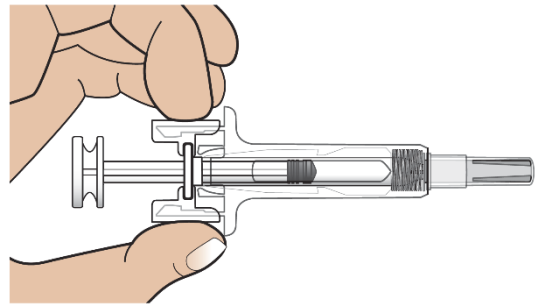
Check the prefilled syringe label to make sure you have the correct strength.

Step 7: Look at the liquid through the viewing window (See Figure H).

- It is normal to see air bubbles. **Do not** flick or try to push the bubbles out.

The liquid should look clear and colorless to pale yellow. **Throw away** the prefilled syringe if the liquid is cloudy, discolored, or has particles in it and use a new prefilled syringe for your injection. See “**Dispose of the used prefilled syringes**” at the end of this Instructions for Use. Call BioMarin at 1-866-906-6100 or your healthcare provider for help with Palynziq.

Figure H



Choose and prepare injection site

Step 8: Choose your injection site.

The recommended injection sites are:

- Front middle of the thighs.
- The abdomen except for the 2 inch (5 centimeter) area directly around the belly button (navel).

If a caregiver is giving the injection, the top of the buttocks and the back of the upper arms may also be used (See Figure I).

- **Do not** inject into moles, scars, birthmarks, bruises, rashes, or areas where the skin is hard, tender, red, damaged, burned, inflamed, or tattooed.
- If you need more than 1 injection for your dose, the injection sites should be at least 2 inches away from each other. The second injection site can be on the same part of the body or a different part of the body (See Figures I and J).
- For each injection, change (rotate) your injection sites. Choose an injection site that is at least 2 inches away from the injection site that you used for the last injection. It can be on the same part of the body or a different part of the body (See Figures I and J).

Step 9: Wash your hands well with soap and water before injecting Palynziq (See Figure K).

Step 10: Clean the chosen site with an alcohol pad. Let the skin air dry for at least 10 seconds before injecting Palynziq (See Figure L).

- **Do not** touch the cleaned injection site.
- **Do not** remove the needle cap until you are ready to inject Palynziq.

Figure I

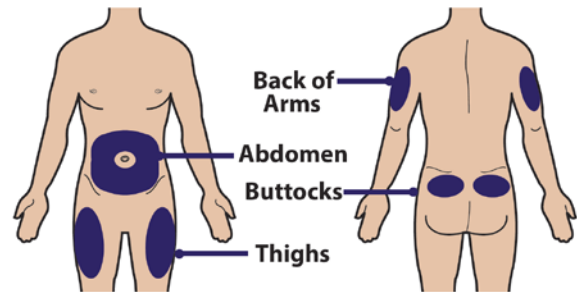


Figure J

Inject at least 2 inches apart

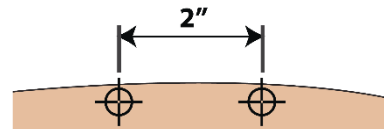
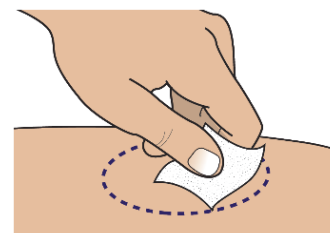


Figure K



Figure L



Inject Palynziq

Step 11: Hold the body of the prefilled syringe with 1 hand with the needle facing away from you (See Figure M).

- **Do not** use the prefilled syringe if it is dropped. **Throw away** the prefilled syringe if it is dropped and use a new prefilled syringe for your injection. See “**Dispose of the used prefilled syringes**” at the end of this Instructions for Use. Call BioMarin at 1-866-906-6100 or your healthcare provider for help with Palynziq.

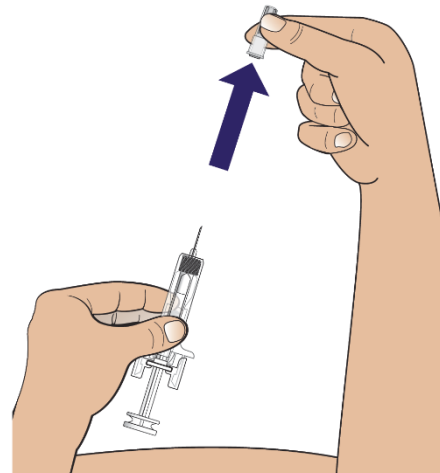
Figure M



Step 12: Pull the needle cap straight off the needle (See Figure N).

- **Do not** twist the needle cap during removal.
- **Do not** hold the prefilled syringe by the plunger or plunger head while taking the needle cap off.
- Before injecting Palynziq, check to make sure that the needle is not damaged or bent. Throw away the prefilled syringe if the needle is damaged or bent and use a new prefilled syringe for your injection. See “**Dispose of the used prefilled syringes**” at the end of this Instructions for Use. Call BioMarin at 1-866-906-6100 or your healthcare provider for help with Palynziq.

Figure N

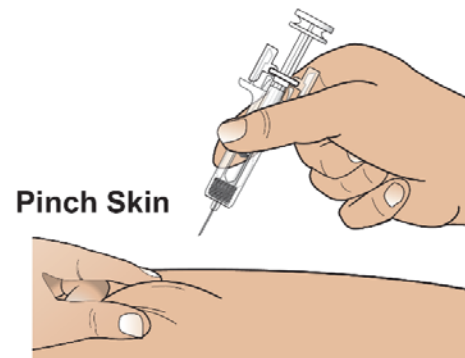


You may see a drop of liquid on the tip of the needle. This is normal. **Do not** wipe it away. Throw the needle cap away in a puncture resistant or sharps disposal container.

Step 13: Hold the body of the prefilled syringe in 1 hand between your thumb and index finger. Use your other hand to pinch up the skin around the injection site. Hold the skin firmly (See Figure O).

- **Do not** touch the plunger head while inserting the needle into the skin.

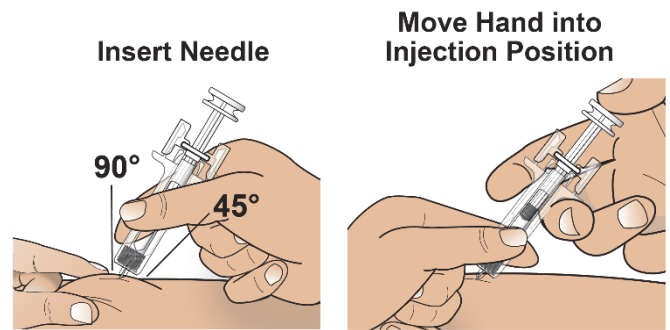
Figure O



Step 14: Use a quick motion to fully insert the needle into the pinched skin at a 45 to 90 degree angle (See Figure P).

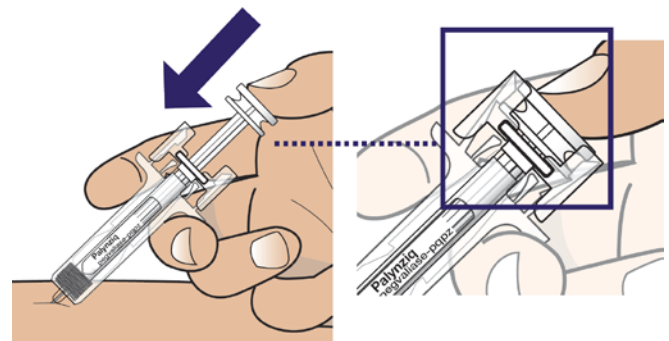
Release the pinch of skin. Use that hand to hold the bottom of the prefilled syringe steady. Place the thumb of your other hand on the plunger head and place your index and middle fingers under the finger grips (See Figure P).

Figure P



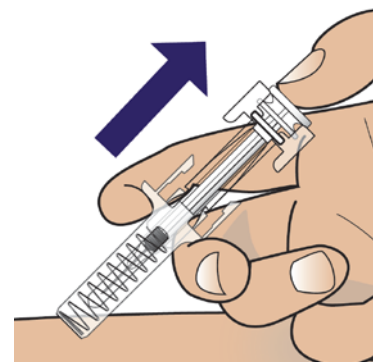
Step 15: Use your thumb to push in the plunger slowly and steadily as far as it will go to inject all the medicine (See Figure Q). **More pressure on the plunger may be needed to inject all the medicine for the 10 mg and 20 mg strength prefilled syringes.**

Figure Q



Step 16: Slowly move your thumb up to release the plunger. The needle will automatically be covered by the prefilled syringe body (See Figure R).

Figure R



Treat injection site

Step 17: Treat injection site (if needed).

If you see drops of blood at the injection site, press a cotton ball or gauze over the injection site and hold for about 10 seconds. You may cover the injection site with a small adhesive bandage if needed.

If more than 1 prefilled syringe is needed for your prescribed dose:

Step 18: If your healthcare provider tells you to use more than 1 prefilled syringe for your prescribed dose, repeat Steps 4 to 17 listed above for each prefilled syringe that you use.

- **Note: Do not** give the injection in the same spot. The injection sites should be at least 2 inches away from each other. See Step 8 for information on choosing an injection site.

If you need to use more than 1 prefilled syringe for your prescribed dose, repeat Steps 4 to 17 right away for each prefilled syringe you use.

Dispose of the used prefilled syringes

Step 19: Put your used prefilled syringes in a puncture resistant container, such as an FDA-cleared sharps disposal container immediately after use (See Figure S).

Do not throw away (dispose of) prefilled syringes in your household trash.

If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- 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,
- leak-resistant, and
- 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

Figure S



permit this. **Do not** recycle your used sharps disposal container.

Note: Keep sharps disposal container out of the reach of children and pets.

Storage of Palynziq

- Store Palynziq in the refrigerator at 36°F to 46°F (2°C to 8°C) (See Figure T).
- If needed, you may store Palynziq at room temperature between 68°F to 77°F (20°C to 25°C) for up to 30 days.
 - Write the date that you remove Palynziq from the refrigerator on the carton.
 - If stored at room temperature, do not put Palynziq back in the refrigerator.
- **Keep Palynziq in the original carton to protect from light.**
- **Do not** freeze or shake Palynziq.
- Throw away Palynziq if it has been kept at room temperature for 30 days and has not been used, or after the expiration date on the carton, whichever comes first.

Figure T



Keep Palynziq and all medicines out of the reach of children.

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

Manufactured by:

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Novato, CA 94949

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