

INSTRUCTIONS FOR USE

VYVGART HYTRULO [viv' gart hye troo' loe]

(efgartigimod alfa and hyaluronidase-qvfc)

injection, for subcutaneous use

1,000 mg and 10,000 units/5 mL

This Instructions for Use contains information on how to inject VYVGART HYTRULO.

Important Information You Need to Know Before Injecting VYVGART HYTRULO

- **VYVGART HYTRULO is for under the skin (subcutaneous) injection only.**
- **Be sure to read and understand this Instructions for Use before injecting VYVGART HYTRULO.** Your healthcare provider should show you or your caregiver how to prepare and inject VYVGART HYTRULO the correct way before using it for the first time. Ask your healthcare provider if you have any questions.
- **The prefilled syringe is for one-time-use only** and cannot be reused.
- **Do not** use VYVGART HYTRULO if it has been at room temperature for longer than 30 days.
- **Do not** use the prefilled syringe if it is expired.
- **Do not** use the prefilled syringe if it is cracked, broken, or damaged. Return damaged prefilled syringes to the specialty pharmacy.
- **Do not** use a prefilled syringe if the liquid medicine is discolored or contains particles. **The liquid medicine should look** clear to yellowish in color. A little cloudiness is normal.
- **Do not** shake the prefilled syringe.
- You will need supplies that are not provided with VYVGART HYTRULO (see Figure J).

Storing VYVGART HYTRULO Prefilled Syringe

- **Store VYVGART HYTRULO in the refrigerator** between 36°F to 46°F (2°C to 8°C) (see Figure A).
- **Keep the prefilled syringes in the original carton** to protect them from light until ready to use.
- **Keep VYVGART HYTRULO and all medicines out of the reach of children.**

Do not freeze the prefilled syringes or store them in direct sunlight.

Do not use a prefilled syringe that has been frozen or left in direct sunlight.

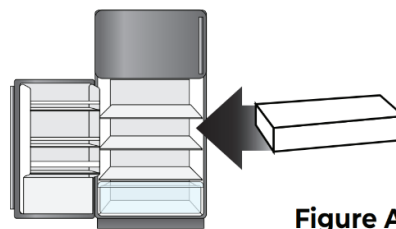
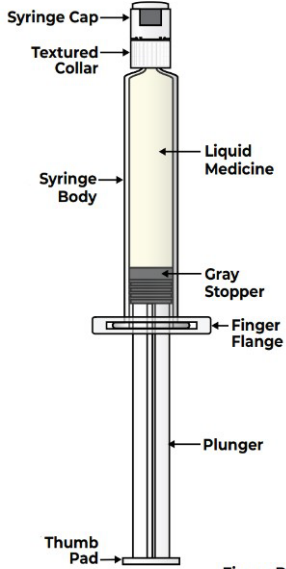
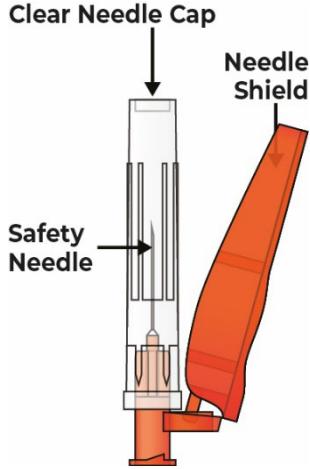


Figure A

Prefilled Syringe Parts

	 <p>Figure B</p>
<p>Safety Needle (not provided with VYVGART HYTRULO prefilled syringe) that is 25G, 5/8 inch length, thin wall</p>	

Gather and Check the Prefilled Syringe

<p>1 Remove the carton from the refrigerator</p>	
---	--

1.1 Remove the carton containing the prefilled syringe from the refrigerator (see Figure C).

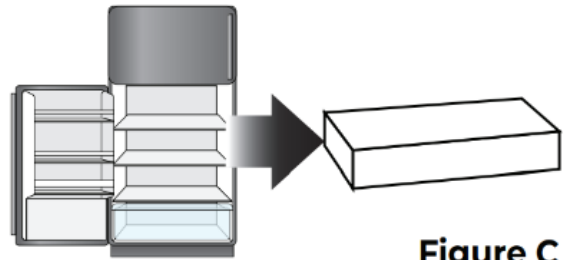


Figure C

1.2 Remove 1 prefilled syringe from the carton (see Figure D) and place any remaining prefilled syringes back into the refrigerator for later use.

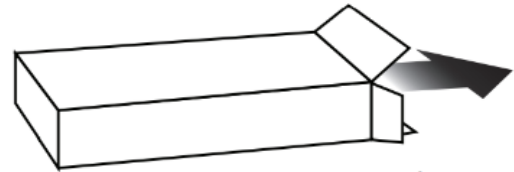


Figure D

1.3 Remove the prefilled syringe from the tray (see Figure E).

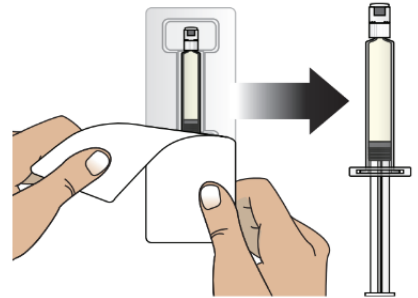


Figure E

2 Check the prefilled syringe before use

2.1 Check the expiration date on the prefilled syringe label (see Figure F).

Do not use the prefilled syringe if the expiration date has passed.

Check the Expiration Date

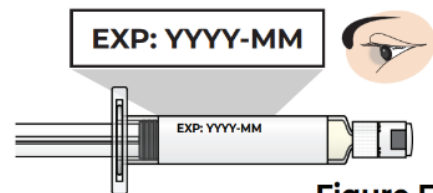
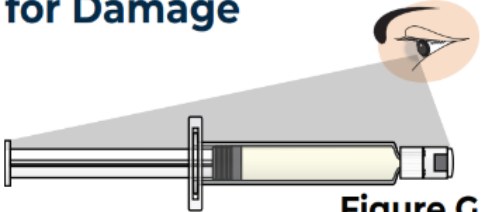
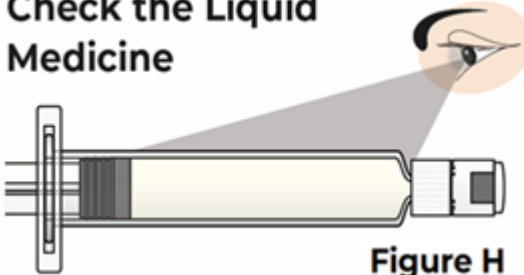
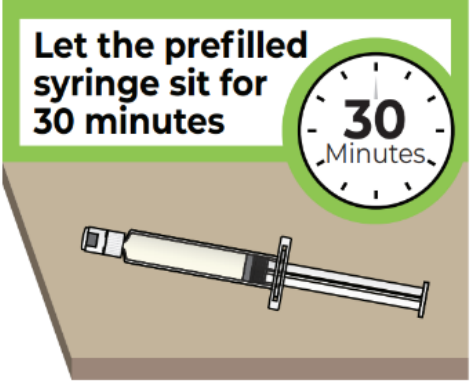


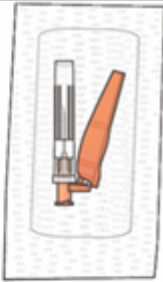



Figure F

<p>2.2 Check the condition of the prefilled syringe and the prefilled syringe cap (see Figure G).</p> <p>Do not use the prefilled syringe if it is cracked, broken, damaged, or if the prefilled syringe cap is missing.</p>	<p>Check the Syringe for Damage</p>  <p>Figure G</p>
<p>2.3 Check the appearance of the liquid medicine in the prefilled syringe (see Figure H).</p> <p>The liquid medicine should look clear to yellowish in color. A little cloudiness is normal.</p> <p>Do not use the prefilled syringe if the liquid medicine is discolored or contains particles.</p>	<p>Check the Liquid Medicine</p>  <p>Figure H</p>

Prepare for the Injection

<p>3 Allow the prefilled syringe to warm to room temperature</p>	
<p>3.1 Place the prefilled syringe on a clean flat surface and let it sit for at least 30 minutes, to allow it to warm to room temperature (see Figure I).</p> <p>Do not attempt to warm the prefilled syringe in any other way.</p> <p>Do not use the VYVGART HYTRULO prefilled syringe if it has been at room temperature for longer than 30 days.</p>	<p>Let the prefilled syringe sit for 30 minutes</p>  <p>Figure I</p>
<p>4 Gather supplies and wash your hands</p>	

4.1 Gather the following supplies that are **not provided** with the prefilled syringe (see Figure J).

- **Safety Needle** 
 - **Alcohol Swab** 
 - **Sharps Disposal Container** 
 - **Sterile Gauze or Small Adhesive Bandage (As Needed)** 
- Figure J**

4.2 Wash your hands with soap and water (see Figure K).

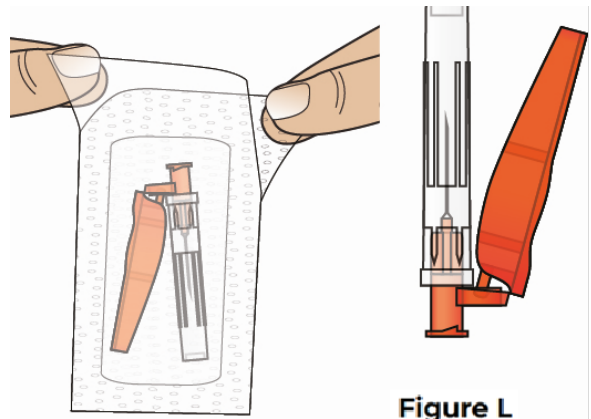


Figure K

5 Snap off the prefilled syringe cap and attach the safety needle

5.1 Carefully open the safety needle package and remove the needle (see Figure L).

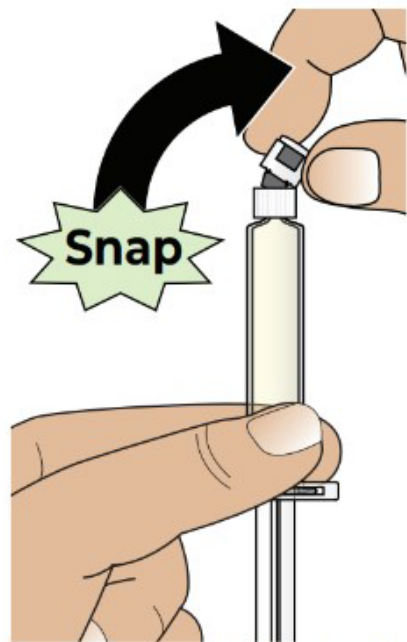
Throw away the packaging into household trash.



5.2 Bend the prefilled syringe cap to one side to snap it off and remove it from the prefilled syringe (see Figure M).

Throw away the prefilled syringe cap into the household trash.

Do not touch the tip of the prefilled syringe after the prefilled syringe cap has been removed.



5.3 Hold the prefilled syringe by the syringe body in one hand, and **attach the safety needle to the prefilled syringe by twisting it to the right (clockwise)** until you feel resistance (see Figure N).

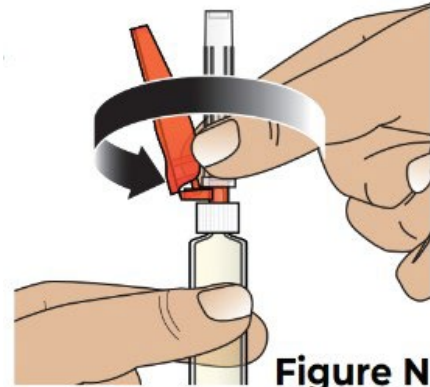


Figure N

The safety needle is now attached to the prefilled syringe (see Figure O).

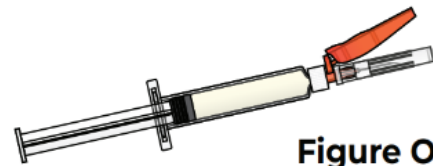


Figure O

6 Choose and clean the injection site on the stomach (abdomen)

6.1 Choose an injection site on the stomach (abdomen) at least 2 inches away from the belly button (navel) (see Figure P).

Change (rotate) the injection site the next time you inject VYVGART HYTRULO.

Do not inject into skin that is irritated, red, bruised, infected, or tender. **Do not** inject into skin that is hard, scarred, or has moles.

Do not inject into a vein. VYVGART HYTRULO is for under the skin (subcutaneous) injection only.

Choose Site on Abdomen

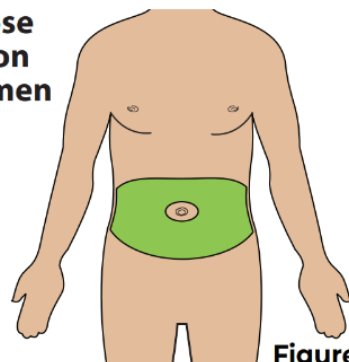


Figure P

6.2 Clean the chosen injection site with an alcohol swab and let it air dry (see Figure Q).

Do not blow on or touch the injection site after it has been cleaned.



Figure Q

Inject VYVGART HYTRULO

7 Pull back the needle shield and remove the clear needle cap

7.1 Pull the needle shield back (see Figure R).

Note: The needle shield will be used after the injection to cover the needle and protect from needle-stick injuries.

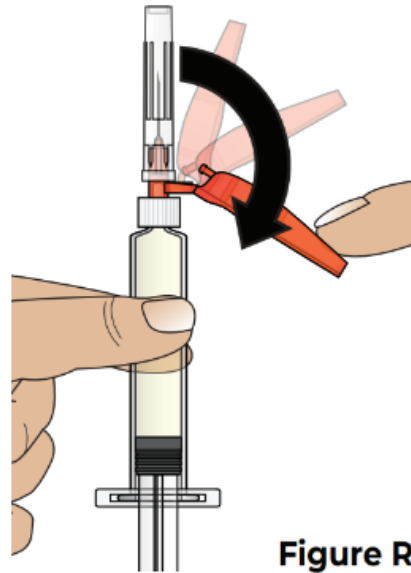


Figure R

7.2 Hold the prefilled syringe body and **remove the clear needle cap by pulling it straight off** of the needle (see Figure S).

Throw away the clear needle cap into the household trash.

Do not recap the needle.

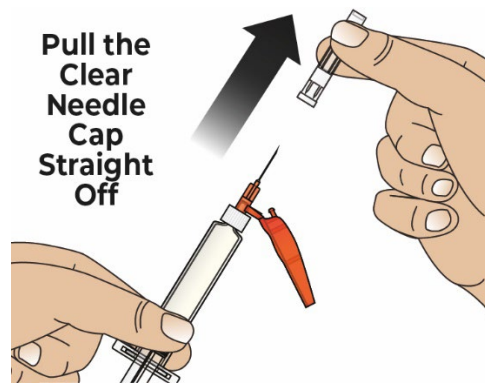


Figure S

8 Give the injection

8.1 Pinch the cleaned injection site (Figure T).

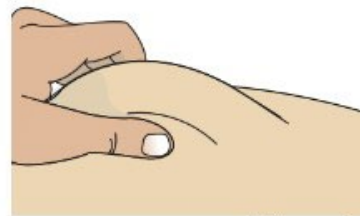


Figure T

While pinching the skin, **insert the needle at a 45 to 90 degree angle** all the way into the pinched skin (see Figure U).

Then release the pinched skin.

Do not pinch the skin too tightly as this can cause bruising.

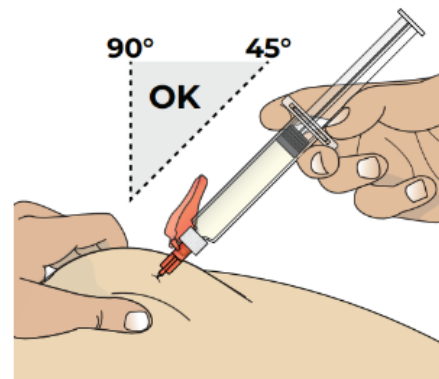


Figure U

8.2 Slowly press the thumb pad down all the way until it stops to inject the liquid medicine (see Figure V).

It will take about 20 to 30 seconds to inject all of the liquid medicine.

You will feel resistance as you press down. Inject more slowly in case there is discomfort.

It is ok if you need to pause or change your grip during the injection.

Do not try to force the thumb pad down quickly as this will make the thumb pad harder to press.

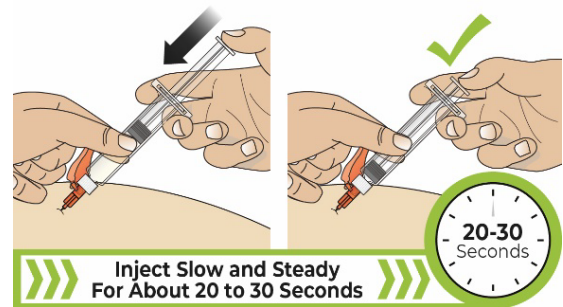


Figure V

8.3 After all the liquid medicine is injected, remove the needle from the skin by pulling it straight out without changing the angle that it was inserted (see Figure W).

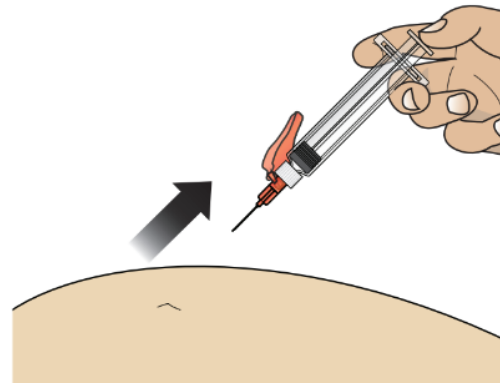
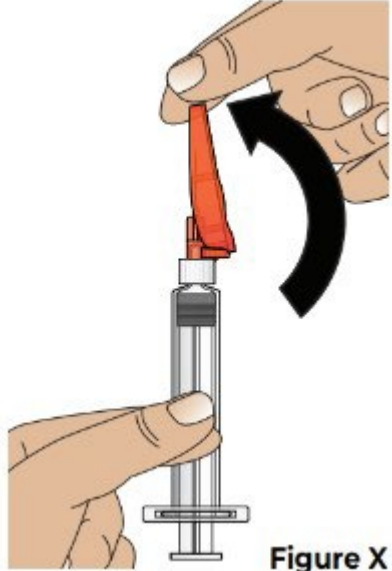



Figure W

Throw away (dispose of) the Used Prefilled Syringe

<p>9 Cover the needle and throw away the used prefilled syringe</p>	
<p>9.1 Carefully push the needle shield over the needle until it snaps into place and covers the needle (see Figure X).</p> <p>This helps to prevent needle-stick injuries.</p> <p>Do not recap the needle using the clear needle cap. Only use the needle shield to cover the needle.</p>	 <p>Figure X</p>
<p>9.2 Throw away the used prefilled syringe, with the needle still attached, into an FDA-cleared sharps disposal container right away after use (see Figure Y).</p> <p>Do not throw away (dispose of) loose needles and syringes in your household trash.</p>	 <p>Figure Y</p>
<p>10 Treat the injection site</p>	

10.1 If there is a small amount of blood or liquid at the injection site, press a sterile gauze over the injection site until the bleeding stops (see Figure Z).

If needed, you may apply a small adhesive bandage.



Figure Z

Additional Disposal Information

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

Always keep the sharps disposal container out of the reach of children.

Additional Information

For more information, go to www.vyvgart.com or call 1-833-898-4278.

Manufactured by:

argenx BV
Industriepark 7
9052 Zwijnaarde, Belgium
U.S. License No. 2217

Halozyme, Inc.
12390 El Camino Real
San Diego, CA 92130
U.S. License No. 2187

Distributed by:

argenx US, Inc.
33 Arch Street
Boston, MA 02110

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

Issued: 4/2025