

Instructions for Use

HumatroPen® 12 mg
(HU-ma-tro-Pen 12 mg)
HUMATROPE® Delivery System Device
for use with
HUMATROPE® (somatropin) 12 mg Cartridges



12 mg

Lilly

Section 1: Read Section 1 completely before you move on to Section 2.

What you need to know about HumatroPen® 12 mg

Read this Instructions for Use including the “Commonly asked questions” section, at the end of this Instructions for Use, before you start using HumatroPen 12 mg and each time you get a new Pen. There may be new information. This information does not take the place of talking to your healthcare provider about your or your child’s medical condition or treatment.

Your healthcare provider should show you how to use HumatroPen (Pen) the right way before you use it for the first time. Ask your healthcare provider if you have any questions.



If you are having problems using the HumatroPen 12 mg, call Lilly at 1-800-545-5979 or go to www.humatrope.com.

Introduction

Intended Use:


- The HumatroPen 12 mg is a reusable pen-injector designed for self-administration of human growth hormone. The pen-injector is intended for use with the specified HUMATROPE 12 mg Cartridges and single use, detachable and disposable pen needles (supplied separately). Your healthcare provider will prescribe the HUMATROPE dose and Pen that is right for you or your child. **Do not** change your dose or use another type of pen unless your healthcare provider tells you to.
- If your healthcare provider changes the prescribed cartridge strength from the 12 mg HUMATROPE Cartridge to the 6 mg or 24 mg HUMATROPE Cartridge, you will need to get a new HumatroPen to match the new cartridge strength.

Contraindications:


There are no known contraindications for HumatroPen 12 mg.

Important information about HumatroPen 12 mg:

- **Do not** use the Pen if any part of the Pen or Cartridge looks broken or damaged. Contact your healthcare provider.
- Make sure that you have a 12 mg HUMATROPE Cartridge to match the HumatroPen 12 mg. If the strength on the label for the Cartridge and the Pen do not match, **do not** use them and contact your healthcare provider. It is important to use the correct Pen and Cartridge to make sure that you inject the correct dose of HUMATROPE.
- **Do not** use the HUMATROPE Cartridge past the expiration date.
- Follow the instructions in Section 2 only to set up a new Cartridge before you use it for the first time.
- Follow the instructions in Section 3 of this Instructions for Use for every injection.
- **Do not** transfer the contents of the HUMATROPE Cartridge to a syringe.

-  **Do not share your HumatroPen 12 mg or Pen Needles with anyone else, even if the Needle has been changed. You may give other people a serious infection or get a serious infection from them.**
- The HumatroPen 12 mg is not recommended for use by blind or visually impaired individuals without the help of a sighted individual trained on how to use it.

Information about Needles used with HumatroPen 12 mg:

- Pen Needles are not included with HumatroPen. You may need a prescription to get the Needles from your pharmacist.
- Becton, Dickinson and Company Pen Needles are recommended for use with the HumatroPen 12 mg.
- Ask your healthcare provider what size Needle is best for you to use.
- Use of the Hidden Needle Cover with your HumatroPen is optional.
- **When using the Hidden Needle Cover with your HumatroPen, you must use a Needle length of 5 mm or longer.**  Read the Hidden Needle Cover Instructions for Use.
- Follow your healthcare provider's instructions about how to safely handle Needles.
- Always remove the Pen Needle after each injection and use a new Needle with each injection. This helps reduce the risk of infection, prevent leakage of HUMATROPE, reduce air bubbles, and reduce Needle clogs.
- **For information on the right way to throw away (dispose of) used Needles** see "Disposing of used Needles" at the end of this Instructions for Use.


How do I care for HumatroPen 12 mg?

- Soiled parts including the Hidden Needle Cover can be cleaned with a damp cloth. **Do not** use alcohol or any other cleaning product.



- Keep dry.
- **Do not** apply oil or any other lubricant.

How do I store HumatroPen 12 mg with an attached cartridge?

-  Store HumatroPen 12 mg between -40°C (-40°F) to 70°C (158°F) without the Humatrope 12 mg Cartridge.
- After attaching a prepared HUMATROPE cartridge to your HumatroPen 12 mg, store it in the storage case in the refrigerator between 36°F to 46°F (+2°C to +8°C) until it is time for your next injection.
- Before injecting a dose of HUMATROPE, take the Pen out of the refrigerator and let it sit for **10 minutes** to allow it to reach room temperature. Injecting medicine that is cold can cause discomfort. Do not leave the HumatroPen 12 mg and HUMATROPE cartridge out of the refrigerator for more than 30 minutes a day.
- HUMATROPE Cartridges attached to a Pen can be stored in the refrigerator for up to 28 days. **Do not** use a prepared Cartridge after 28 days.
- **Do not** freeze.
- **Do not** store the Pen with the Needle attached.
- Protect HUMATROPE Cartridges attached to the Pen from light during storage.

When do I need to replace and dispose my HumatroPen?

Do not use your pen for more than 3 years after the first use or past the Use-by date on the carton, whichever comes first.

The expired Pen may be discarded in your household trash after you have removed the Needle.

Record the date the Pen was first used here: ___ / ___ / ___.

Record the Use-by date from your carton here: ___ / ___ / ___.

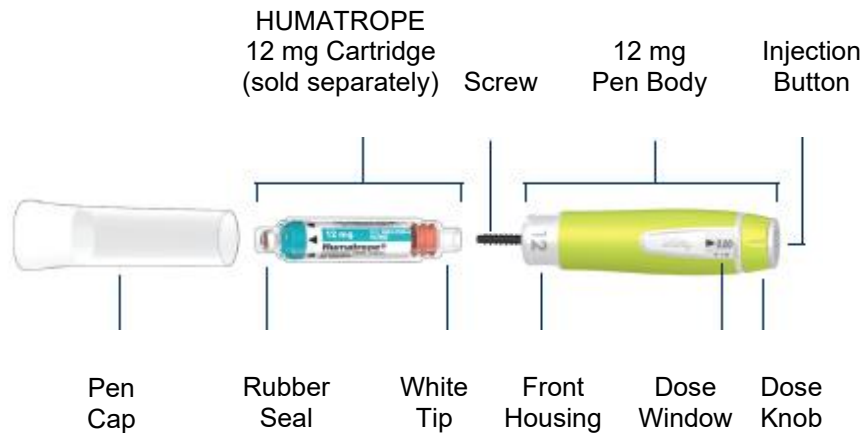
Contact your healthcare provider if you need a new HumatroPen 12 mg, or when the Pen has been used for 3 years.



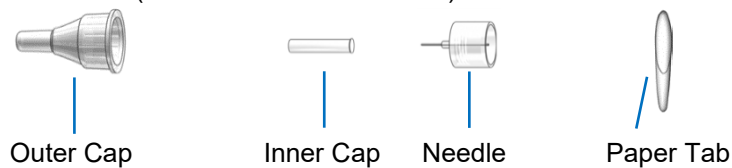
Please see the accompanying complete Humatrope *Patient Information Sheet*.

For more information, call Lilly at 1-800-545-5979 or go to www.humatrope.com.

HumatroPen 12 mg Parts



Pen Needle Parts (Pen Needles not included)



Hidden Needle Cover (optional, included)



Storage Case



Section 2: Read Section 2 only after you have read Section 1.

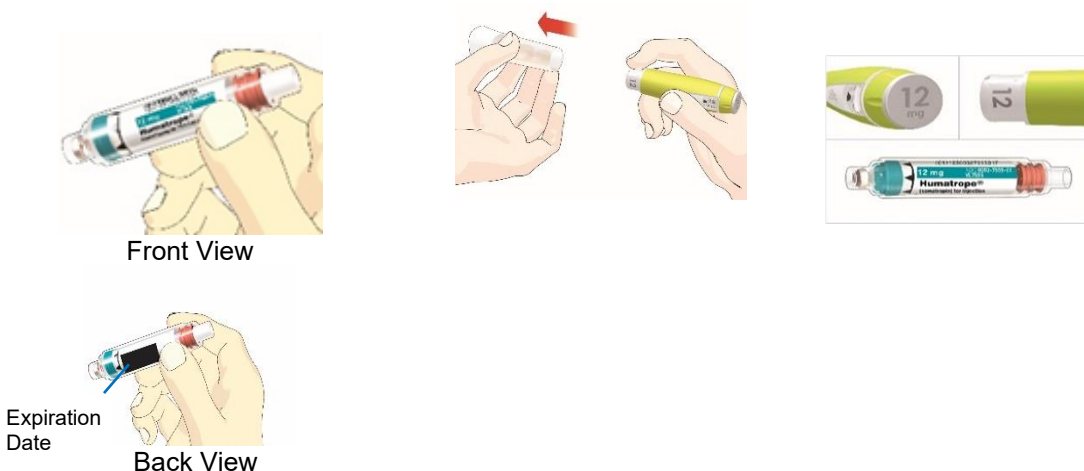
Getting Started

- Be sure to follow the reconstitution (mixing) directions in the HUMATROPE Cartridge Kit.
- Perform the New Cartridge Set-up only **1** time at the beginning of each new Cartridge preparation.

- For daily use, **do not repeat** the 1 time only New Cartridge Set-up. If you repeat the 1 time only New Cartridge Set-up, you may run out of HUMATROPE early.

New Cartridge Set-up

Step 2A – Check the Pen and Cartridge



- Be sure to check the Cartridge:
 - For 12 mg on the Cartridge Label
 - For the expiration date on the opposite side of the Cartridge
 - To see if the liquid is clear and free of particles

Important Notes:

- Do not** use the Cartridge past the expiration date.
- Do not** use the Pen if any part of the Pen or Cartridge appears broken or damaged. Contact your healthcare provider.

- Pull off the Pen Cap.

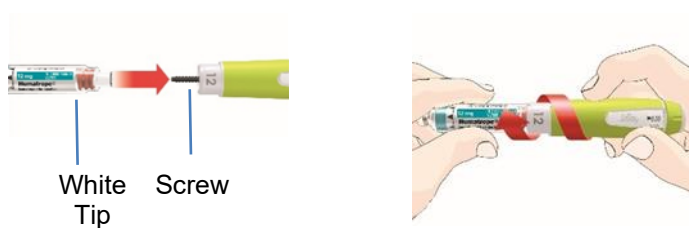
- Look at the Injection Button and the Front Housing to make sure it is a 12 mg Pen.

Important Note:



Check the number on the Front Housing to make sure that it matches the Cartridge strength on the Cartridge label. If the Pen and Cartridge do not match, contact your healthcare provider.

Step 2B – Attach the Cartridge



- The screw may be in or out when you get the Pen.
- Push the white tip of the mixed Cartridge into the Pen body. Screw the 12 mg Pen body onto the Cartridge until it is secure.

- If the screw is out, use the white tip of the Cartridge to push the screw back.

Important Note:
If the Cartridge is not completely attached, the screw may not move, and cause you to inject the wrong dose.

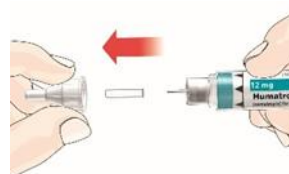
Step 2C – Attach the Needle



- Remove the paper tab from the end of the Outer Cap.

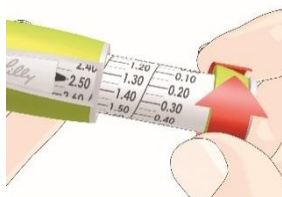


- Push the Needle **straight** onto the 12 mg Cartridge and turn it until secure.

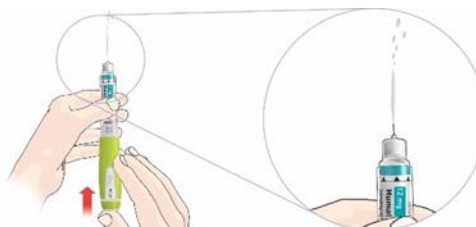


- Pull off the Outer Cap and the Inner Cap.
- Keep the Outer Cap to remove the Needle after the injection.

Step 2D – Remove air from new Cartridge



- Turn the dose knob to dial 2.50 mg.



- Point the Needle straight up.
- Push the Injection Button and hold it for **5** seconds.
- Dial 0.10 mg and repeat these steps until liquid is seen at the Needle tip.

Important Notes:

- The Pen must be set-up before injecting the first dose from each new 12 mg Cartridge.
- Setting up the new Cartridge is important to remove large air bubbles that may be present after mixing the HUMATROPE 12 mg Cartridge.
- If liquid is not seen at the Needle tip after you have tried several times to remove air from the new Cartridge as instructed in Step 2D, contact your healthcare provider or Lilly at 1-800-545-5979.

Step 2E – Continue on to Daily Use

- **Do not** repeat the New Cartridge Set-up before each dose.
- Leave the Cartridge attached and **do not** remove it until the Cartridge is empty.
- If you are ready to inject the first dose and you have finished setting up your Pen with a new Cartridge, go to Section 3, Step 3C.
- If you are using the Hidden Needle Cover with HumatroPen 12 mg, read the Hidden Needle Cover Instructions for Use.

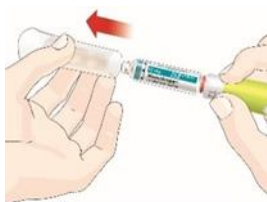
Section 3: Now that you have done the 1 time only New Cartridge Set-up, follow Section 3 for each of your daily injections.

- Remove the prepared Pen with the Cartridge attached from your refrigerator.
- Let the Pen with Cartridge attached stand at room temperature for **10** minutes before injecting.

Daily Use

Before your injection: Take the Pen out of the refrigerator and let it sit for **10 minutes before injecting** to allow it to reach room temperature. Injecting medicine that is cold can cause discomfort.

Step 3A – Check the Pen



- Pull off the Pen Cap.

Important Note:

Do not use the Pen if any part of the Pen or Cartridge appears broken or damaged. Contact your healthcare provider.



- Be sure to check the Cartridge:
 - For 12 mg Cartridge label
 - For expiration date
 - To see if the liquid is clear and free of particles

Important Note:

Do not use the Cartridge past the expiration date.



- Look at the Injection Button and the Front Housing to make sure it is a 12 mg Pen.

Important Note:



Check the number on the house Front Housing to make sure that it matches the Cartridge strength on the Cartridge label. If the Pen and Cartridge do not match, contact your healthcare provider.

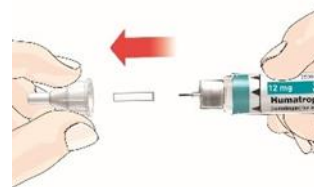
Step 3B – Attach a new disposable Pen Needle for each injection.



- Remove the paper tab from the end of the Outer Cap.



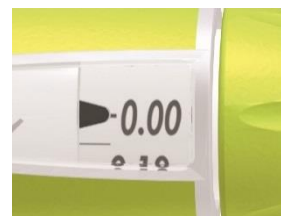
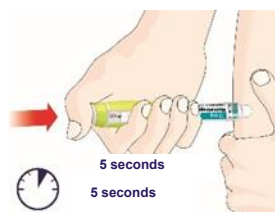
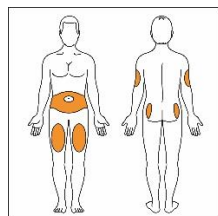
- Push the Needle **straight** onto the 12 mg Cartridge and turn it until secure.



- Pull off the Outer Cap and the Inner Cap.
- Keep the Outer Cap to remove the Needle after the injection.

Important Note: Talk to your healthcare provider about the right way to use the Pen, and the optional Hidden Needle Cover, the right sites to inject HUMATROPE, and how to rotate your injection sites. When using the Hidden Needle Cover with your HumatroPen, you must use a Needle length of 5 mm or longer. Read the Hidden Needle Cover Instructions for Use.

Step 3C – Dial and inject the dose



- Turn the dose knob to the prescribed dose.

Important Note:

Confirm the dose dialed matches the prescribed dose. Your dose may be different than the dose shown in the figure above.

- If you turn past the prescribed dose, you can correct the dose by turning down to the right dose.
- The dose knob clicks as you turn it. **Do not** dial your dose by counting clicks because you may dial the wrong dose.

- Injections can be given under the skin (subcutaneous) in the following areas:

- Abdomen: above, below, or either side of the belly button (navel)
- Front of the upper thighs
- Upper, outer buttocks
- Back of the arms above the elbow and below the shoulder

- Talk to your healthcare provider about the right way to use HumatroPen, the right areas to give your injection, and injection site rotation.

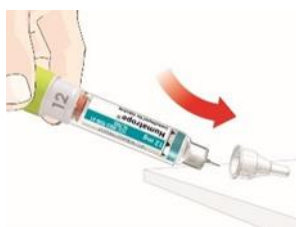
- Insert the Needle at a 90 degree angle or as shown by your healthcare provider.
- Place your thumb on the Injection Button, then slowly and firmly push the injection button until it stops moving.
- Continue to hold the Injection Button for **5** seconds, then remove the Needle from the skin.
- Check to make sure you see a **0.00** in the dose window. This means that the complete dose was injected.


Important Note:

It is possible to set a dose larger than the amount of HUMATROPE left in the Cartridge.

- At the end of the injection, the number in the dose window should be **0.00**. If you see any number other than "0.00", this is the amount of HUMATROPE you **did not receive**. Write this number down and follow the steps below to get the rest of your dose.
- Remove the Needle and empty Cartridge from the Pen.
- **Repeat Steps 2A through 2D.**
- Complete your dose by injecting only the amount you **did not receive**.
- If you still do not think you received your full dose, **do not** take another dose. Call Lilly at 1-800-545-5979 or call your healthcare provider for assistance.

Step 3D – Remove and dispose of the Needle



-  Carefully replace the Outer Needle Cap as instructed by your healthcare provider.
 - You can use the scoop method: Scoop the Outer Cap back on the Needle.
- Remove the capped Needle. Follow the instructions in the “Disposing of used Needles” section at the end of this Instructions for Use to dispose of the Needle.
- Replace the Pen Cap.

Important Note: Do not remove this Cartridge from the Pen until the Cartridge is empty or needs to be replaced to help prevent you from giving the wrong dose.

Step 3E – Store Pen and Cartridge for next use

- See, “How do I store HumatroPen 12 mg?” in Section 1 of this Instructions for Use for more information.
- When it is time for the next scheduled dose, go to Section 3, and repeat Steps 3A through 3D.
- When using the Hidden Needle Cover with HumatroPen 12 mg, repeat steps 1 to 10 of the Hidden Needle Cover Instructions for Use.

Commonly asked questions:

1. Do I need to perform the New Cartridge Setup before every dose?

- No. You only need to perform the New Cartridge Set-up 1 time for each Cartridge, just before a new Cartridge is used for the first time.
- The purpose of the New Cartridge Set-up is to make sure the HumatroPen 12 mg with an attached HUMATROPE 12 mg Cartridge are ready to use.
- If you repeat the New Cartridge Set-up before each routine dose, you may run out of HUMATROPE early. The small amount of medicine used in the New Cartridge Set-up will not affect the amount of HUMATROPE in the Cartridge.

2. What should I do if the Cartridge label and Pen do not match?

- **Do not use** the Pen if the Cartridge strength on the HUMATROPE Cartridge label does not match the number on the Pen's Front Housing. This is important to make sure the correct dose of HUMATROPE is given.
- Contact your healthcare provider for a replacement.

3. What should I do if the HUMATROPE is not clear?

- **Do not use** the Pen if the liquid is cloudy or contains particles. Contact your healthcare provider or call Lilly at 1-800-545-5979 or go to www.humatrope.com.

4. Why are there air bubbles in the Cartridge?

- Air bubbles may remain in the Cartridge after mixing.
- If the Pen is stored with a Needle attached, air bubbles may form in the Cartridge. **Do not store** the Pen with a Needle attached.
- Follow the instructions in Section 2, Step 2D (Remove air from new Cartridge) to remove air bubbles from the Cartridge.
- It is normal to see small air bubbles. It will not cause any harm or affect the dose.

5. What should I do if the screw does not move out when there is no Cartridge attached to the Pen?

- The screw may not move out when you push the Injection Button unless there is a Cartridge in the Pen. This allows you to easily push the screw into the Pen Body when replacing a Cartridge.
- After a Cartridge is attached, the screw will move out when the Injection Button is pushed.

6. What should I do if I cannot attach the Cartridge to the Pen Body?

- Check that the Cartridge is not damaged or broken.
- Carefully line up the Cartridge with the Pen Body and screw them together until secure. If the Cartridge and Pen cannot be screwed together, contact your healthcare provider.

7. Why is it hard to push the Injection Button when I try to inject the dose?

- The Needle may be clogged. Try attaching a new Needle.
- Pushing the Injection Button down quickly may make the Injection Button harder to push. Pushing the Injection Button more slowly may make it easier.
- Using a larger Needle will make it easier to push the Injection Button during injection. Ask your healthcare provider which Needle is best for you.
- The Injection Button may become harder to push if the inside of the Pen gets dirty with HUMATROPE, food, drink, or other materials.

8. What should I do if the dose knob does not go to zero (0) when I inject the dose?

- This can happen if the HUMATROPE Cartridge does not have enough HUMATROPE left in it for the full dose.
- At the end of the injection, the number in the dose window should be **0.00**. If you see any number other than “0.00”, this is the amount of HUMATROPE you **did not receive**. Write this number down and follow the steps below to get the rest of your dose.
- To get the rest of your dose:
 - Remove the Needle and empty Cartridge from the Pen.
 - Insert a new Cartridge, attach a new Needle, and remove air from the new Cartridge (see Steps 2A through 2D).
 - Complete your dose by injecting only the amount you **did not receive** (see Step 3C).
 - If you still do not think you received your full dose, **do not** take another dose. Call Lilly at 1-800-545-5979 or your healthcare provider for assistance.

9. What should I do if I see HUMATROPE leaking from the Needle after I have finished the injection?

- It is normal for a single drop to remain on the tip of the Needle after the injection is complete. If you see more than 1 drop:
 - The full dose may not have been delivered. **Do not inject** another dose. Talk with your healthcare provider for assistance.
 - To prevent this, for the next dose, firmly push and hold the Injection Button in and slowly count to **5** (see Section 3, Step 3C).

10. How can I tell when the injection is complete?

- The injection is complete when:
 - You place your thumb on the injection Button, then slowly and firmly push the Injection Button until it **stops moving**.
 - Continue to hold the Injection Button for **5** seconds, then remove the Needle from the skin.
 - **You will see 0.00** in the center of the dose window.


If you have any questions or problems with your HumatroPen 12 mg, contact Lilly at 1-800-545-5979 or your healthcare professional for assistance.

Report all MEDICAL DEVICE COMPLAINTS or UNDESIRABLE SIDE EFFECTS, including SUSPECTED SERIOUS INCIDENTS, to Eli Lilly and Company, by contacting them at 1-800-545-5979.

You are also encouraged to report all UNDESIRABLE SIDE EFFECTS, including SUSPECTED SERIOUS INCIDENTS, to the U.S. FOOD & DRUG Administration (US FDA) by:

- Visiting the MedWatch web page on reporting an adverse event or serious problem to FDA at (<https://www.fda.gov/safety/reporting-serious-problems-fda/how-consumers-can-report-adverse-event-or-serious-problem-fda>) or
- Calling FDA’s toll-free information line at 1-800-INFO-FDA (1-888-463-6332).

Disposing of used Needles:

-  Put your used Needles in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose Needles in your household trash.**
- If you do not have a 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. **Do not** reuse or share your Needles with other people. 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.

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

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Eli Lilly and Company
Pharmaceutical Delivery Systems
Lilly Corporate Center
Indianapolis, IN 46285, USA
US License Number 1891



Eli Lilly Nederland B.V.
Papendorpseweg 83
3528 BJ UTRECHT
The Netherlands

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The HumatroPen® 12 mg meets the current dose accuracy and functional requirements of ISO 11608-1 and is for use with HUMATROPE® 12 mg Cartridges only.

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Revised December 2023

Non-harmonized Symbol Glossary¹

	Patient information website
	Medical Device ²
	Single Patient – Multiple Use ²
	Unique device identifier ²

¹ Glossary includes non-harmonized symbols used in the labeling.

² Symbol used only on the carton.