



PA005PEY04

HumatroPen® 6 mg

Growth Hormone Delivery System
Injection Device for Use with
Humatrope® (somatropin) Cartridges



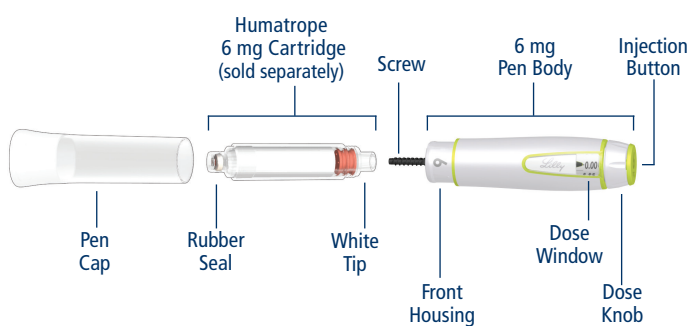
6 mg

PEN USER MANUAL

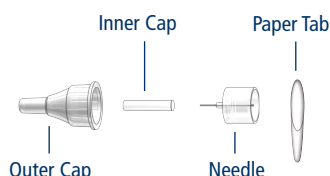


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HUMATROPEN 6 MG PARTS



PEN NEEDLE PARTS (PEN NEEDLES NOT INCLUDED)



Section 1

Read this section completely before you begin. Then, move on to Section 2.

WHAT YOU NEED TO KNOW ABOUT THE HUMATROPEN® 6 MG

Read these instructions carefully BEFORE using your HumatroPen® 6 mg. You need to use the Pen correctly in order to get the most benefit from the Humatrope® treatment. Failure to follow these instructions completely may result in too much or too little Humatrope being injected.

INTRODUCTION

Intended Use:

The HumatroPen 6 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 6 mg Cartridges and single use, detachable and disposable pen needles (supplied separately).

Contraindications:

There are no known contraindications for HumatroPen 6 mg

Your healthcare professional has prescribed the Humatrope dose and Pen that you or your child should receive.

DO NOT CHANGE the dose or Pen unless directed by your healthcare professional.

Before using your HumatroPen 6 mg, make sure that you thoroughly read this pen user manual. It explains the Pen operations and has a troubleshooting guide, should questions arise.

These instructions do not take the place of talking with your healthcare professional about your medical condition or your treatment. If you have questions, or problems using your HumatroPen 6 mg, contact your physician, pharmacist or nursing staff or your local Lilly affiliate (see last page for contact details).

IMPORTANT INFORMATION ABOUT THE HUMATROPEN 6 MG

- DO NOT USE the Pen if any part of the Pen or Cartridge appears broken or damaged. Contact your physician, pharmacist or nursing staff.
- Confirm that you have a 6 mg Humatrope Cartridge to match the HumatroPen 6 mg. If it does not match DO NOT USE and contact your physician, pharmacist or nursing staff.
- Follow Section 2 ONLY to set up a new Cartridge before first use.
- Section 3 of this manual should be used for every injection.
- DO NOT SHARE** your HumatroPen 6 mg or Pen Needles as this may risk transmission of infectious agents.
- The HumatroPen 6 mg is not recommended for use by blind or visually impaired individuals without the assistance of a sighted individual trained in its use.

ABOUT PEN NEEDLES

What kinds of Needles can be used with the HumatroPen 6 mg?

- Pen Needles are not included. You may need a prescription to get the Needles from your pharmacist.
- Becton, Dickinson and Company (BD) Pen Needles are recommended for use with the HumatroPen 6 mg.
- 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 greater. Refer to the Hidden Needle Cover Instructions for use
- Ask your physician, pharmacist or nursing staff what Needle gauge and length is best for you.

Must a new Needle be used for each injection?

- Yes, a new Needle must be used for each injection.
- Remove the Needle immediately after each injection. Use a new Needle for each injection. This will help minimize the risk of infection, prevent leakage of Humatrope, keep out air bubbles, and reduce Needle clogs.

How do I throw away used Needles?

- Throw away used Needles as directed by your physician, pharmacist or nursing staff.

CARE AND STORAGE FOR THE HUMATROPEN 6 MG

Care

- Soiled parts can be cleaned with a damp cloth. DO NOT USE alcohol or other cleaning agents.
- DO NOT APPLY oil or any other lubricant.

Storage

- Store HumatroPen 6 mg between -40°C to 70° C without the Humatrope (somatropin) 6 mg Cartridge.
- Store the HumatroPen 6 mg with attached Humatrope Cartridge in the storage case in the refrigerator until the time of the next injection. DO NOT FREEZE.
- Refer to the Humatrope cartridge Patient Information Leaflet for complete storage instructions.
- Let the HumatroPen 6 mg with attached Humatrope Cartridge stand at room temperature for 10 minutes before injecting. Discomfort may be noticed at the injection site if Humatrope is injected cold.
- Daily room temperature exposure should not exceed 30 minutes.
- DO NOT STORE the Pen with the Needle attached.

REPLACEMENT and DISPOSAL OF PEN

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 waste after you have removed the needle. Ask your healthcare professional about options to dispose of the pen properly.

Record the date the Pen was first used here: ___/___/___.
Record the Use-by date from your carton here: ___/___/___.

Contact your physician, pharmacist or nursing staff if a new HumatroPen 6 mg is needed, or when the Pen has been used for 3 years.

Please see the accompanying complete Humatrope Patient Information Sheet.

For additional information, contact your physician, pharmacist or nursing staff or your local Lilly affiliate (see last page for contact details) or visit our website at www.lilly.co.uk

Section 2

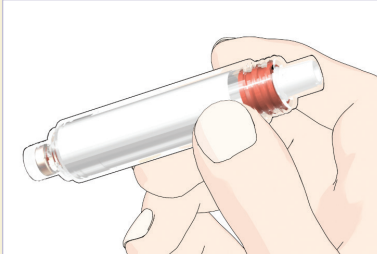
Read and follow the directions in this section only after you have read Section 1.

GETTING STARTED

Be sure to follow the reconstitution (mixing) directions as described in the Humatrope Cartridge Kit. Perform the New Cartridge Setup only once at the beginning of each new Cartridge. For daily use, **DO NOT REPEAT** the New Cartridge Setup. If you do, you may run out of Humatrope early.

NEW CARTRIDGE SETUP

STEP A - CHECK THE PEN AND CARTRIDGE

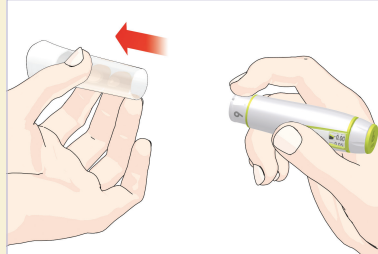


Be sure to check the Cartridge:

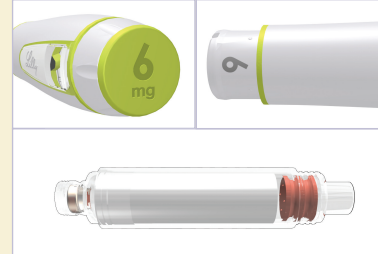
- For 6 mg Cartridge Label
- For expiration date
- Contents should be clear and free of particles

NOTE

DO NOT USE the Pen if any part of the Pen or Cartridge appears broken or damaged. Contact your physician, pharmacist or nursing staff.



Pull off the Pen Cap.



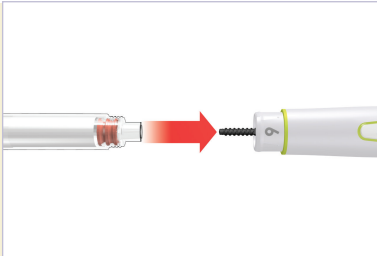
Look at the Injection Button and the Front Housing to confirm it is a 6 mg Pen.



CHECK

Check that the number on the Front Housing matches the Cartridge strength on the Cartridge label. If the Pen and Cartridge do not match, contact your physician, pharmacist or nursing staff.

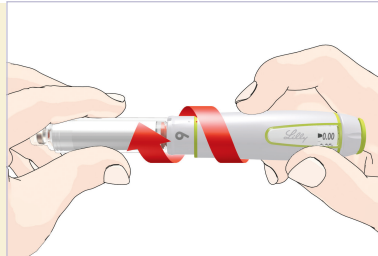
STEP B - ATTACH THE CARTRIDGE



Use the White Tip of the Cartridge to push the Screw back.

NOTE

The screw may not be out when you get the Pen.



Push the White Tip of a reconstituted Cartridge into the Pen Body. Screw the 6 mg Pen Body onto the Cartridge until it is secure.

NOTE

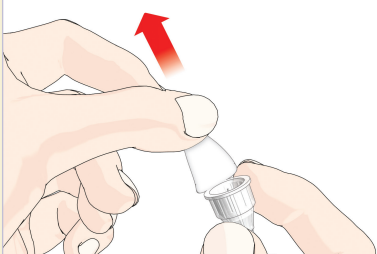
If the Cartridge is not completely attached, the Screw may not move, and an incorrect dose may be given.



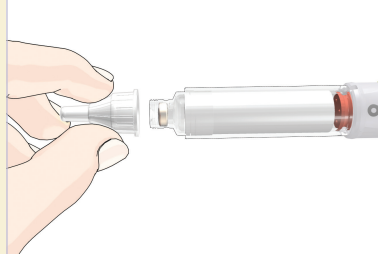
CHECK

Look at the Injection Button, the Front Housing and cartridge label to confirm it is a 6 mg Pen.

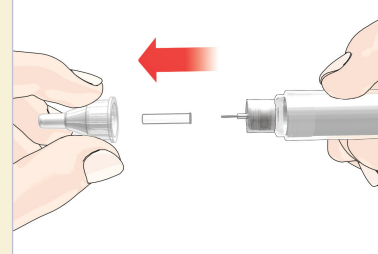
STEP C - ATTACH THE NEEDLE



Remove the Paper Tab from the end of the Outer Cap.

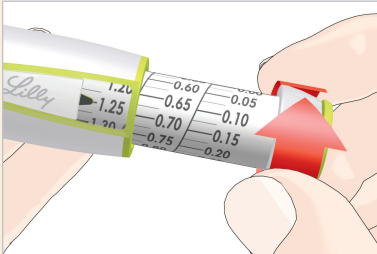


Push the Needle straight onto the 6 mg Cartridge and screw on clockwise until secure.

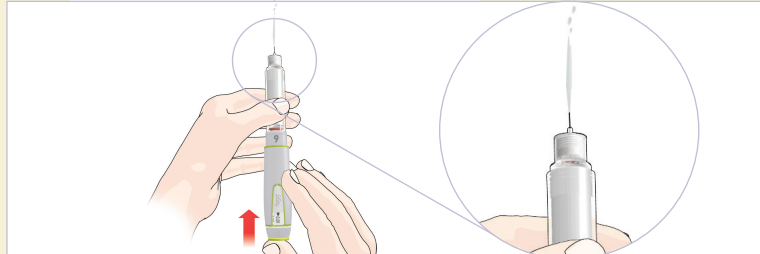


- Pull off the Outer Cap and the Inner Cap.
- Keep the Outer Cap to remove the Needle after your injection.

STEP D - REMOVE AIR FROM NEW CARTRIDGE



Dial 1.25 mg.



- Point the Needle straight up.
- Push the Injection Button and hold for five seconds.
- Dial 0.05 mg and repeat these three steps until you see a stream of liquid.

NOTE

- The Pen must be set up before injecting the first dose from each new 6 mg Cartridge.
- Setting up the new Cartridge is important to remove large air bubbles that may be present after reconstitution (mixing).
- If a stream is not seen after several attempts, contact your physician, pharmacist or nursing staff or your local Lilly affiliate (see last page for contact details).

STEP E - CONTINUE ON TO DAILY USE

- DO NOT REPEAT Cartridge Setup before each dose.
- Leave the Cartridge attached and DO NOT REMOVE until the Cartridge is empty.
- Go to Section 3, Step 3, for instructions on how to inject the first dose.

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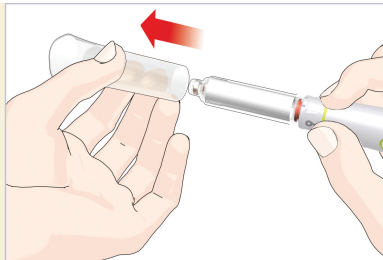
Section

3

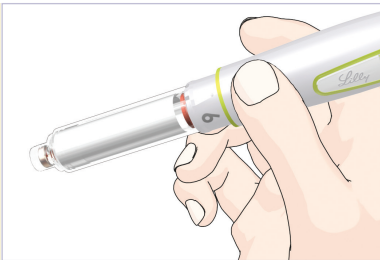
Now that you have done the one-time New Cartridge Setup, follow Section 3 for all of your injections.

DAILY USE

STEP 1 - CHECK THE PEN

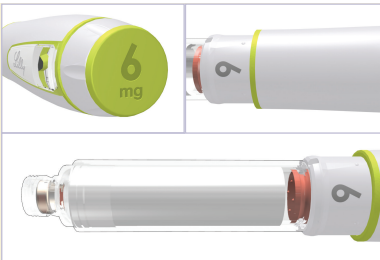


Pull off the Pen Cap.



Be sure to check the Cartridge:

- For 6 mg Cartridge Label
- For expiration date
- Contents should be clear and free of particles



Look at the Injection Button and the Front Housing to confirm it is a 6 mg Pen.

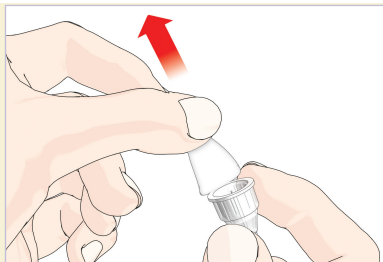
NOTE

DO NOT USE the Pen if any part of the Pen or Cartridge appears broken or damaged. Contact your physician, pharmacist or nursing staff.

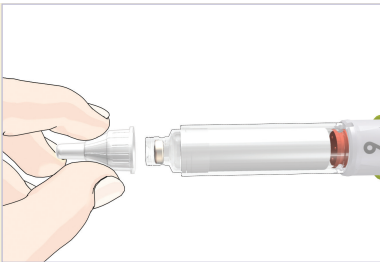
CHECK

Check that the number on the Front Housing matches the Cartridge strength on the Cartridge label. If the Pen and Cartridge do not match, contact your physician, pharmacist or nursing staff.

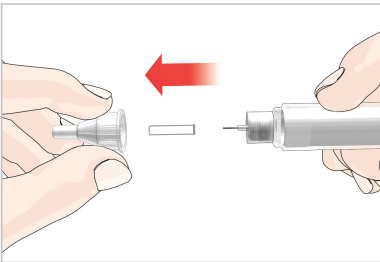
STEP 2 - ATTACH THE NEEDLE



- Remove the Paper Tab from the end of the Outer Cap.



Push the Needle **straight** onto the 6 mg Cartridge and screw on clockwise until secure.



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

NOTE

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 greater. Refer to the Hidden Needle Cover Instructions for Use

STEP 3 - DIAL AND INJECT THE DOSE



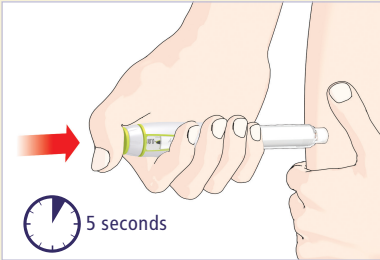
Turn the Dose Knob to desired dose.

EXAMPLE

0.25 mg shown in the drawing above.

If you dial past the desired dose, you can correct the dose by dialing backwards.

The dose knob clicks as you turn it. **DO NOT** dial your dose by counting clicks because you may dial the wrong dose.

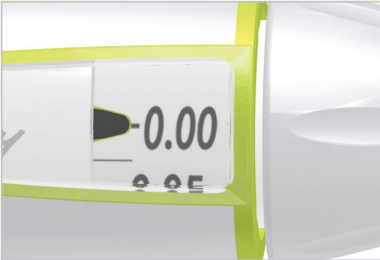


Insert the Needle as directed by your physician, pharmacist or nursing staff.

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 **five** seconds, then remove the Needle from the skin.

Check to make sure you see a **0.00** in the Dose Window to confirm you received the complete dose.



NOTE

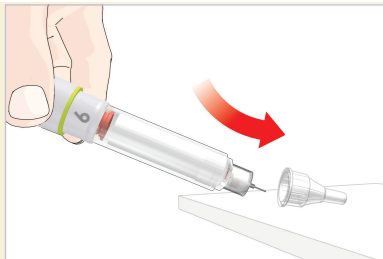
It is possible to set a dose larger than the amount of Humatrope left in the Cartridge.

At the end of the injection, the number in the Dose Window should be **0.00**. If it is not, this is the amount of Humatrope you **DID NOT** receive.

Consult with your physician, pharmacist or nursing staff on how to handle a partial dose. Remove the Needle and empty Cartridge.

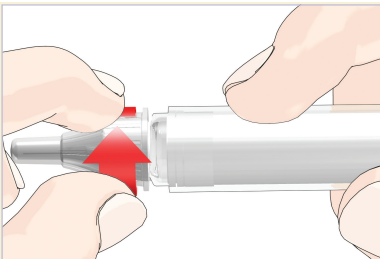
For the next daily use attach a new Cartridge as shown in Section 2, Step A, and continue with New Cartridge Setup (Section 2).

STEP 4 - REMOVE AND DISPOSE OF THE NEEDLE

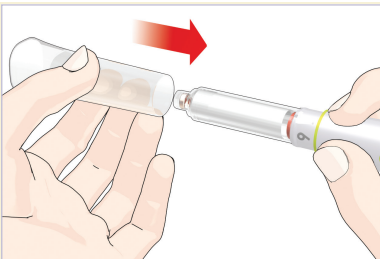


NOTE

Carefully replace the Outer Needle Cap as instructed by your physician, pharmacist or nursing staff.



- Remove the capped Needle by turning anti-clockwise.
- **NOTE** Put used needles in a sharps container or a hard plastic container with a secure lid. Do not throw Needles directly into your household waste.
- Do not recycle the filled sharps container.
- Ask your physician, pharmacist or nursing staff about options to dispose of the sharps container properly.



Replace the Pen Cap.

- **DO NOT STORE** the Pen with a Needle attached - this helps prevent air from entering the Cartridge.
- **DO NOT REMOVE** this Cartridge from the Pen until the Cartridge is empty or needs to be replaced - this will help to avoid the possibility of an inaccurate dose.

STEP 5 - STORE PEN AND CARTRIDGE FOR NEXT USE

Store the HumatroPen 6 mg properly. (See "Care and Storage for the HumatroPen 6 mg" in **Section 1** of this pen user manual for more information.)

When it is time for your next dose, go to Section 3, and repeat Steps 1 -5.

Section

4

COMMONLY ASKED QUESTIONS

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

- No. The New Cartridge Setup is done only once for each Cartridge, just before a new Cartridge is used for the first time.
- The purpose of the setup is to make sure the HumatroPen 6 mg with the Humatrope 6 mg Cartridge are ready to use.
- If you repeat the New Cartridge Setup before each routine dose, you may run out of Humatrope early. The small amount of product used in the New Cartridge Setup will not affect the supply of Humatrope.

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.
- Contact your physician, pharmacist or nursing staff for assistance or to obtain a replacement.

3. What should I do if the Humatrope is not clear after mixing?

- Be sure to gently invert the Pen up and down 10 times. **DO NOT SHAKE**. Then, let the Pen sit for at least three minutes. If the solution remains cloudy or has particles, gently invert the Pen up and down 10 more times. Let the Pen sit for five more minutes.
- If the solution remains cloudy or contains particles after reconstitution (mixing), **DO NOT USE**. Contact your physician, pharmacist or nursing staff for assistance.

4. Why are there air bubbles in the Cartridge?

- Air bubbles may remain in the Cartridge after reconstitution (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.
- Perform the New Cartridge Setup to remove air bubbles from the Cartridge.
- A small air bubble is normal. It will not harm you nor affect the dose.

5. Why doesn't the Screw 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 feature allows you to easily push the Screw into the Pen Body when replacing a Cartridge.
- Once a Cartridge is attached, the Screw will move out when the Injection Button is pushed.

6. What should I do if I can't 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 together until secure. If the Cartridge and Pen cannot be screwed together contact your physician, pharmacist or nursing staff.

7. Why is it difficult 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 diameter Needle, for example a 12.7mm Needle (diameter 0.33mm) will make it easier to push the Injection Button during injection. Ask your physician, pharmacist or nursing staff which Needle is best for you.
- The Injection Button may become harder to push if the inside of your Pen gets dirty with Humatrope, food, drink or other materials.

8. Why doesn't the Dose Knob go to zero when I inject the dose?

- This can happen if the Humatrope Cartridge does not have enough Humatrope left in it for the full dose. 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 it is not, this is the amount of Humatrope you DID NOT receive. Consult with your physician, pharmacist or nursing staff on how to handle a partial dose. Remove the Needle and empty Cartridge. For the next daily use attach a new Cartridge as shown in Section 2, Step A, and continue with New Cartridge Setup (Section 2).

9. Why do 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 one drop:
 - You may not have received your full dose. **DO NOT INJECT** another dose. Consult with your physician, pharmacist or nursing staff for assistance.
 - To prevent this, for your next dose, firmly push and hold the Injection Button in and slowly count to **five** (see Section 3, Step 3).

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

- The injection is complete when:
 - You have slowly counted to five while you are still holding the Injection Button in and before you remove the Needle from the skin.

AND

- 0.00 is in the center of the Dose Window.

If you have any questions or problems with your HumatroPen 6 mg, contact local Lilly affiliate office (see below) or your healthcare professional for assistance.

Report all MEDICAL DEVICE COMPLAINTS or UNDESIRABLE SIDE EFFECTS including SUSPECTED SERIOUS INCIDENTS, to local Lilly affiliate office (see below).

You are also encouraged to report all UNDESIRABLE SIDE EFFECTS, including SUSPECTED SERIOUS INCIDENTS to United Kingdom: Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Australia: www.tga.gov.au/reporting-problems

Malta: ADR Reporting, Website: www.medicinesauthority.gov.mt/adportal

South Africa: <https://www.sahpra.org.za/Publications/Index/8>

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The HumatroPen® 6 mg meets the current dose accuracy and functional requirements of ISO 11608-1 and is for use with Humatrope® 6 mg Cartridges only.

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Non-harmonized Symbol Glossary¹

	Patient information website
	Medical device²
	Single patient – multiple use²

¹ Glossary includes non-harmonized symbols used in the labeling.
² Symbol used only on the carton.

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