## Instructions for Use

**NATPARA® (nat-PAH-rah)**
(parathyroid hormone)
for injection for subcutaneous use

### Medicine Cartridge Tracker

<table>
<thead>
<tr>
<th>Cartridge 1</th>
<th>Cartridge 2</th>
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<tbody>
<tr>
<td><strong>Date Mixed</strong></td>
<td><strong>Discard On</strong></td>
</tr>
<tr>
<td><em><strong>/</strong></em>/___</td>
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### Instructions:

1. Enter today’s date in the space next to “Date Mixed.”
2. Enter the date 14 days from today in the “Discard On” section.
3. Dispose of your medicine cartridge on the “Discard On” date even if you have medicine left in the cartridge.

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

Manufactured for:
Shire-NPS Pharmaceuticals, Inc.
300 Shire Way
Lexington, MA 02421
USA
1-800-828-2088

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Q-Cliq™ is a trademark of Shire-NPS Pharmaceuticals, Inc.

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What if the stoppers do not stay together after mixing?
- The Pen Needle may not be on correctly.
- Make sure that the Pen Needle is on the right way and that the threads are lined up. Be sure that the needle is firmly attached. You may need to use a new Pen Needle.

What if I have more than a few drops on the tip of the Pen Needle after injection?
This may mean that you did not hold the needle in your thigh for the full 10 seconds. When you give your next scheduled injection, be sure that you hold the needle in your thigh for at least 10 seconds.

What should I do if there are many small bubbles after mixing the NATPARA medicine cartridge?
It is normal to see small air bubbles in the liquid after you finish mixing your NATPARA medicine.

What should I do if the liquid is colored?
Call 1-800-828-2088 for help.

What should I do if the liquid has small particles in it?
It is normal to sometimes see small particles.

How do I clean my Q-Cliq™ pen and mixing device?
If needed, clean the Q-Cliq pen and mixing device by wiping them with a damp cloth. Do not place the Q-Cliq pen and mixing device in water, or wash them with any liquid, such as alcohol.

Can I reuse the Pen Needle?
Do not reuse your Pen Needle. You must use a new Pen Needle for each injection.
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Your Q-Cliq™ pen can be re-used for up to 2 years. See Figure A.
The rod protector protects the rod during shipment from the factory. Throw away the rod protector when you are ready to use your Q-Cliq pen.

Your NATPARA Medicine Cartridge:
• Your NATPARA medicine cartridge contains medicine powder and a liquid to mix the powder in. See Figure B. You must mix the powder and the liquid in the medicine cartridge before using your Q-Cliq pen.
• Each medicine cartridge contains 14 doses.
• The dose indicator shows you the number of doses left in the medicine cartridge.
Getting to Know the Parts of Your Q-Cliq™ Pen and Your NATPARA Medicine

Other supplies you will need to give your NATPARA. See Figure C.

- 31G x 8 mm BD Ultra-Fine™ Pen Needle:
  - The needle is covered with a needle guard
  - The paper tab seals the needle and the needle guard in the needle cap
- puncture resistant sharps container
- 1 alcohol swab
- mixing device
- NATPARA Medicine Cartridge Tracker (see front cover fold out of your NATPARA booklet)

![Figure C](image)

Use the **alcohol swab** to clean the injection area.

**Figure C**

- Medicine Cartridge Tracker
- Wheel
- Rod (extended)

(Puncture-resistant container example)

- Mixing Device
- Wheel
- Rod (extended)

- Needle Cap
- Paper Tab
- Needle Guard
- Needle

- (Exploded view)

- Other supplies you will need to give your NATPARA.
- 31G x 8 mm BD Ultra-Fine™ Pen Needle:
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- mixing device
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Preparing and Mixing Your NATPARA

• Mix your NATPARA 1 time every 14 days.
• If this is your first time using NATPARA by yourself, a trainer will call you and guide you through how to mix your first NATPARA medicine cartridge and also your second medicine cartridge.

Step 1.
Wash and dry your hands.

Step 2.
Gather your supplies, including:
• your mixing device
• new NATPARA medicine cartridge from the refrigerator
• new disposable Pen Needle
• puncture-resistant sharps container
• pencil or pen
• Medicine Cartridge Tracker

Step 3.
Look at the Medicine Cartridge Tracker in the front of your NATPARA booklet.

Step 4.
Write the date in the space next to “Date Mixed.” See Figure D.

Step 5.
Write the date 14 days from the day you mixed NATPARA in the space next to “Discard on.” This will be the same day of the week 2 weeks later. See Figure E.

• Do not use your NATPARA on or after the “Discard on” date even if there is medicine left in the cartridge.
• Throw away the empty medicine cartridge when it is time to prepare your new cartridge.
• A Pen Needle must be attached to mix a new cartridge.
Step 6.
Remove the paper tab from the needle cap. See Figure F.

Step 7.
While keeping the needle cap straight, screw it firmly onto the cartridge in a clockwise direction.
Do not remove the needle cap or guard until you are ready to give your medicine. See Figure G.

Step 8.
Turn the wheel of the mixing device in a counterclockwise direction to lower the rod if it is not already lowered. See Figure H.

- Make sure the rod in the mixing device looks like this. See Figure I.

Step 9.
Screw the cartridge onto your NATPARA mixing device in a clockwise direction. The Pen Needle must be attached. See Figure J.
Step 10. With the needle cap pointing up, turn the wheel slowly in a clockwise direction until the stoppers no longer move. **Make sure the wheel turns easily.** See Figure K.

Step 11. Make sure the stoppers look like this and stay together. **See Figure L.**

Step 12. Mix the powder by slowly moving the cartridge back and forth about 10 times. **Do not** shake the cartridge. **See Figure M.**
Step 13.
Set the mixing device down with the medicine cartridge attached. Wait until the powder is dissolved and the liquid is colorless, or 5 minutes have passed. It is normal to see small particles in the liquid.

Step 14.
If the liquid is colorless, go to Step 15. If the liquid is not colorless, call 1-800-828-2088 for help.
You will prepare your Q-Cliq™ pen 1 time every 14 days.

**Step 15.**
Pick up your Q-Cliq pen and remove the cap. Save the cap for later use. **See Figure N.**

**Step 16.**
Unscrew the rod protector or the empty medicine cartridge in a counterclockwise direction and throw it away in a puncture-resistant sharps container. **See Figure O.**

**Step 17.**
Press the injection button. You should see the “0” line up with the notch in the dose window. If you do not see the “0” line up, press the injection button until it is lined up. **See Figure P.**

**Step 18.**
Lower the rod. If the rod is extended, turn the dark red ring counterclockwise to lower it. Do not tighten the ring too much. **See Figure Q.**
Preparation of Your Q-Cliq™ Pen

Step 19. Check the rod. It will have a small space when done the right way. See Figure R.

Step 20. Pick up the mixing device with the needle cap pointing up. Unscrew the cartridge from the mixing device in a counterclockwise direction and set the mixing device down. See Figure S.

Step 21. Attach the medicine cartridge to the pen. Pick up the Q-Cliq pen base and hold it with the rod pointed upright. See Figure T.

Step 22. With the needle cap pointing up, screw the medicine cartridge onto the Q-Cliq pen in a clockwise direction until there is no space between the medicine cartridge and the Q-Cliq pen. See Figure U.
Preparation of Your Q-Cliq™ Pen

**Step 23.**
Turn the dosage knob until “GO” lines up with the notch in the dose window.
See Figure V.

**Step 24.**
Hold the Q-Cliq pen with the needle cap pointing up.
See Figure W.

**Step 25.**
Press the injection button on a flat surface, such as a tabletop, until the “0” lines up with the notch in the dose window.
See Figure X.
- It is normal for 1 or 2 drops of liquid to leak out during this step.
- **Do not** remove the medicine cartridge from the Q-Cliq pen until the “Discard on” date or the medicine cartridge is empty.
- Prime your Q-Cliq pen only 1 time for each new medicine cartridge.
• If you have just finished mixing your medicine and preparing your Q-Cliq pen and the Pen Needle is on, go to Step 33.
• If you need help at any time, call 1-800-828-2088.

Step 26.
Wash and dry your hands.

Step 27.
Gather your supplies, including:
• your Q-Cliq pen from the refrigerator
• new disposable Pen Needle
• puncture resistant sharps container

Step 28.
Check the medicine cartridge. See Figure Y.

Step 29.
Remove the cap from the Q-Cliq pen. The mixed medicine cartridge should be inside.

Step 30.
If the liquid is colorless go to Step 31. It is normal to see small particles in the liquid. If the liquid is not colorless, call 1-800-828-2088 for help.
Giving Your Daily NATPARA

Attaching a new Pen Needle

Step 31. Remove the paper tab from the needle cap. See Figure Z.

Step 32. While keeping the needle cap straight, screw it firmly onto the medicine cartridge in a clockwise direction. Do not remove the needle cap or needle guard until you are ready to give your NATPARA. See Figure AA.

Step 33. Clean the area of your thigh where you will give NATPARA with an alcohol swab. Use a different thigh every time you give your NATPARA. See Figure BB.
Make sure the needle cap is pointing downward at all times during Step 34 to Step 39.

Step 34.
Hold the Q-Cliq pen with the needle cap **pointing down until after your injection.**
See Figure CC.

Step 35.
Hold the Q-Cliq pen so you can see the dose window.
See Figure DD.

Step 36.
Turn the dosage knob until “GO” lines up with the notch in the window. **Do not** turn the dosage knob past “GO.”
See Figure EE.

- If the dosage knob is **hard to turn,** you may not have enough liquid left. Check the **dose indicator** on the medicine cartridge to see if there are any doses left or check the “**Discard on**” date on the **Medicine Cartridge Tracker** to see if it has been more than **14 days.**
Step 37.  
Gently tap the medicine cartridge 3 to 5 times.  
See Figure FF.

Prepare the Pen Needle for giving the injection

Step 38.  
Pull the needle cap off and set it aside. Make sure you do not unscrew the needle cap. Pull the needle guard off and throw it away.  
See Figure GG.

Giving your NATPARA Injection

Step 39.  
Hold the Q-Cliq pen so you can see “GO” in the dose window with the Pen Needle pointing down.  
See Figure HH.

Step 40.  
Insert the Pen Needle fully into your thigh. Make sure you can see “GO” in the window.  
See Figure II.
Step 41.
Press the injection button until the “0” lines up with the notch in the dose window. You should see and feel the dosage knob turn back to “0.”
See Figure JJ.
- Slowly count to 10.
- Keep the Pen Needle in your skin for 10 seconds after pressing the injection button to make sure you get your full dose.

Step 42.
Remove the Pen Needle from your skin by pulling it straight out.
- It’s normal for 1 or 2 drops of liquid to leak out during this step.
- If you do not think you received your full dose, do not take another dose. Call your doctor. You may need to take calcium and active vitamin D.

Step 43.
Carefully put the large needle cap back on the Pen Needle by scooping the cap back on the needle using only 1 hand.
See Figure KK.
Step 44.
Unscrew the needle cap (with Pen Needle inside) in a counterclockwise direction while holding the medicine cartridge. See Figure LL.

- Do not share your Q-Cliq pen or Pen Needles with anyone else. You may give an infection to them or get an infection from them.

Step 45.
Discard your used needles and medicine cartridges.

- Put your used needles and medicine cartridges in an FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and medicine cartridges in your household trash. See Figure MM.

- 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
– 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. 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.

Step 46.

Put the cap back on your Q-Cliq pen.

• A medicine cartridge must be attached to the pen before you can put the pen cap on.

• Line up the pocket clip on the cap with the tab on the Q-Cliq pen. See Figure NN.

• Press the cap and Q-Cliq pen together until you hear it click.
Giving Your Daily NATPARA

Step 47.
Put your Q-Cliq pen in the refrigerator.

How should I store NATPARA?

- **Unmixed NATPARA medicine cartridges:** Refrigerate NATPARA between 36°F to 46°F (2°C to 8°C). **Do not freeze.**

- **Mixed NATPARA medicine cartridges:**
  - Refrigerate between 36°F to 46°F (2°C to 8°C). **Do not freeze.**
  - You can use the Q-Cliq pen for up to 14 days after mixing the medicine cartridge.
  - Throw away the mixed NATPARA medicine cartridges 14 days after mixing the medicine cartridge.

- Store NATPARA away from heat and light.

- **Do not** freeze or shake NATPARA. **Do not** use NATPARA if it was frozen or shaken.

Keep NATPARA and all medicines out of the reach of children.
There are 4 ways to get your questions answered:
• Call your healthcare provider.
• Visit our Web site at www.NATPARA.com.
• Call 1-800-828-2088.
• Find it in the following list of questions.

What does the dose window in the Q-Cliq™ pen tell me?
The dose window tells you if the Q-Cliq pen is ready for the injection:
• "0" means not ready
• "GO" means ready
• The dose window does not count the number of doses left or given

Why does the dose indicator scale on the medicine cartridge show “14” after I have given an injection using a newly mixed NATPARA medicine cartridge?
You might have forgotten to prime the Q-Cliq pen. See Step 23 in the “Preparing Your Q-Cliq™ Pen,” section of the Instructions for Use. Call 1-800-828-2088 for help.

What if the dosage knob is hard to turn to “GO”?
• Do not use force if the knob will not easily turn to “GO.” You may have used your last dose.
• Check the dose indicator on the medicine cartridge to see if there are any doses left, or check the “Discard on” date on the Medicine Cartridge Tracker to see if it has been more than 14 days.
• If the cartridge contains at least 1 dose, call 1-800-828-2088 for help.
What should I do if the NATPARA medicine cartridge is frozen, whether or not it is attached to the Q-Cliq pen?

Throw away the frozen medicine cartridge and mix a new medicine cartridge.

Why do I not throw away the medicine cartridge on day 14 after giving the last injection?

A medicine cartridge or the “dummy” rod protector is needed to put the cap on the Q-Cliq pen. After injecting yourself on day 14, leave the current medicine cartridge on the Q-Cliq pen, put the pen cap back on, and store the pen in the refrigerator. The next day, which will be day 15, throw away the old medicine cartridge and mix a new one.

What if the newly mixed NATPARA medicine cartridge is hard to screw onto the Q-Cliq pen?

• The rod in the Q-Cliq pen may be extended.
• Remove the cartridge and make sure that the rod is fully lowered. If it is not fully lowered, turn the dark red ring to lower it until the ring stops. **Do not** tighten it too much. Reattach the cartridge and see if it is easier to attach.
• If it is still too hard to screw onto the Q-Cliq pen, check to see if the stoppers in the cartridge window are together.
• If the stoppers are together, call 1-800-828-2088 for help.
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What if I have more than a few drops on the tip of the Pen Needle after injection?
This may mean that you did not hold the needle in your thigh for the full 10 seconds. When you give your next scheduled injection, be sure that you hold the needle in your thigh for at least 10 seconds.

What should I do if there are many small bubbles after mixing the NATPARA medicine cartridge?
It is normal to see small air bubbles in the liquid after you finish mixing your NATPARA medicine.

What if the liquid is colored?
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