

Instruct patients to promptly report signs and symptoms of possible osteosarcoma such as persistent localized pain or occurrence of a new soft tissue mass that is tender to palpation.

17.2 NATPARA REMS

[see Warnings and Precautions (5.1, 5.2)]

- NATPARA is available only through a restricted program called the NATPARA REMS Program, because of the potential risk of osteosarcoma.
- Counsel patients on the benefits and risks of NATPARA using the NATPARA Patient Brochure.
- Patients must sign the NATPARA REMS Patient-Prescriber Acknowledgment Form.
- Provide patient with a copy of the NATPARA Patient Brochure and NATPARA REMS Patient-Prescriber Acknowledgment Form.
- NATPARA is only available through certified pharmacies, provide information to your patients about how they will receive prescriptions:
 - Submit the NATPARA prescription to the NATPARA REMS Program Coordinating Center (by fax or email).
 - The REMS Program Coordinating Center will send the prescription to a certified pharmacy to fill after verifying that the prescriber is certified and a Patient-Prescriber Acknowledgment Form is on record.
 - The REMS Program Coordinating Center will call the patient and provide the name and phone number of the certified pharmacy that will be dispensing NATPARA.
 - The certified pharmacy will contact the patient to arrange the date to ship NATPARA once the prescription is filled.

17.3 Severe Hypercalcemia

[see Warnings and Precautions (5.3)]

Instruct patients that severe hypercalcemia can occur when starting or adjusting NATPARA dose and/or when making changes to co-administered drugs known to raise serum calcium. Instruct patients to: report symptoms of hypercalcemia promptly, report any changes to co-administered drug(s) known to influence calcium levels and follow recommended serum calcium monitoring.

17.4 Severe Hypocalcemia

[see Warnings and Precautions (5.4)]

Instruct patients that severe hypocalcemia can occur if NATPARA dosing is abruptly interrupted or discontinued. Instruct patients to report symptoms of hypocalcemia promptly, report interruption in NATPARA dosing and follow recommended serum calcium monitoring. In the event of NATPARA dose interruption, patients should contact their healthcare provider, as their doses of active vitamin D and calcium supplementation may need adjustment.

Medication Guide
NATPARA® (nat-PAH-rah)
(parathyroid hormone)
for injection

What is the most important information I should know about NATPARA?

NATPARA may cause serious side effects, including:

- **possible bone cancer (osteosarcoma).** During animal drug testing, NATPARA caused some rats to develop a bone cancer called osteosarcoma. It is not known if people who take NATPARA will have a higher chance of getting osteosarcoma. Tell your doctor right away if you have pain in any areas of your body that does not go away, or any new or unusual lumps or swelling under your skin that is tender to touch. These are some of the signs and symptoms of osteosarcoma and your doctor may need to do further tests.
 - **NATPARA is only available through the NATPARA Risk Evaluation and Mitigation Strategy (REMS) Program.** The purpose of the NATPARA REMS program is to inform patients about the potential risk of osteosarcoma associated with the use of NATPARA. For more information about this REMS program, call 1-855-628-7272 or go to www.NATPARAREMS.com.
- **high blood calcium (hypercalcemia).** NATPARA can cause some people to have a higher blood calcium level than normal. Your doctor should check your blood calcium before you start and during your treatment with NATPARA. Tell your doctor if you have nausea, vomiting, constipation, low energy, or muscle weakness. These may be signs that you have too much calcium in your blood.
- **low blood calcium (hypocalcemia).** People who stop using or miss a dose of NATPARA may have an increased risk of severe low blood calcium levels. Tell your doctor if you have tingling of your lips, tongue, fingers and feet, twitching of face muscles, cramping of feet and hands, seizures, depression, or have problems thinking or remembering.

Tell your doctor right away if you have any of these signs and symptoms of high or low blood calcium levels.

What is NATPARA?

- NATPARA is a prescription parathyroid hormone (PTH) used with calcium and vitamin D to control low blood calcium (hypocalcemia) in people with low PTH blood levels (hypoparathyroidism).
- NATPARA is only for people who do not respond well to treatment with calcium and active forms of vitamin D alone, because it may increase the possible risk of bone cancer (osteosarcoma).
- NATPARA was not studied in people with hypoparathyroidism caused by calcium-sensing receptor mutations.
- NATPARA was not studied in people who get sudden hypoparathyroidism after surgery.

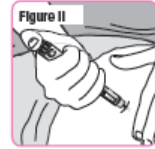
It is not known if NATPARA is safe and effective for children 18 years of age and younger. NATPARA should not be used in children and young adults whose bones are still growing.

Before you start using NATPARA, tell your doctor about all of your medical conditions, including if you:

- have Paget's disease or other bone disease
- have or have had cancer in your bones
- have or have had radiation therapy
- have or had too much calcium in your blood
- have high blood levels of certain electrolytes (alkaline phosphatase)
- are pregnant or plan to become pregnant. It is not known if NATPARA will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if NATPARA passes into your breast

Giving your NATPARA Injection

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.**



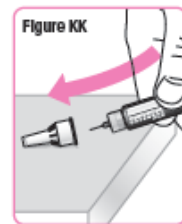
- Slowly count to **10**.
- Keep the Pen Needle in your skin for **10** seconds after pressing the injection button to make sure you get your full dose.



Step 42. Remove the Pen Needle from your skin by pulling it straight out.

- It is 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.



After your injection:

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.



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.

Frequently Asked Questions

There are 4 ways to get your questions answered:

- Call your healthcare provider.
- Visit our Website at www.NATPARA.com.
- Call 1-855-NATPARA (1-855-628-7272).
- 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 1-855-NATPARA (1-855-628-7272) 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 1-855-NATPARA (1-855-628-7272) 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 1-855-NATPARA (1-855-628-7272) for help.

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 1-855-NATPARA (1-855-628-7272) 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.

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

NPS Pharma
550 Hills Drive
Bedminster, NJ 07921

1-855-NATPARA (1-855-628-7272)



Revised: 12/2015