

## Important Reminders on How to Mix and Administer NATPARA



### What is NATPARA<sup>®</sup> (parathyroid hormone) for Injection?

- NATPARA is a prescription parathyroid hormone used with calcium and vitamin D to control low blood calcium (hypocalcemia) in people with low parathyroid hormone 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.

### Important Safety Information

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

##### Warning: 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.
- **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-NATPARA (628-7272) or go to [www.NATPARAREMS.com](http://www.NATPARAREMS.com).

Please see Important Safety Information throughout.

Please click [here](#) for Full Prescribing Information, Medication Guide, and Instructions for Use for NATPARA.

### PLEASE NOTE:

- This brochure contains important information and explanations to remember while using NATPARA. ***It does not replace the full Instructions for Use.***
- Follow the Instructions for Use **every time you mix your NATPARA medicine cartridge, prepare your Q-Cliq™ pen, or give an injection** so you do not forget to do a step.
- **Please see accompanying full Prescribing Information, including the Medication Guide and the Instructions for Use for NATPARA.** The Instructions for Use can be found online at [www.NATPARA.com](http://www.NATPARA.com) and are included with your NATPARA medicine.

## Important Safety Information

### What is the most important information I should know about NATPARA? (cont'd)

#### NATPARA may cause other serious side effects, including:

##### 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.

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Please click here for [Full Prescribing Information, Medication Guide, and Instructions for Use for NATPARA.](#)



(Actual size)

## What you need to know about using NATPARA

NATPARA is available as an injection (shot). You will need to inject NATPARA once a day directly under the skin of the thigh. Be sure to inject a different thigh every day.

Use NATPARA exactly as your doctor tells you to. Do not stop taking or change your dose of NATPARA unless your doctor tells you to. Your calcium level could become dangerously low.

If you miss a day or forget to give your daily NATPARA injection, give your injection as soon as you remember and call your doctor right away. You may need to take more calcium. Take your next dose of NATPARA the next day as prescribed.

If you use more than your daily dose of NATPARA, call your doctor right away.

### Before starting NATPARA, talk to your doctor and review the Medication Guide and Instructions for Use.

Hypoparathyroidism is a rare disorder that occurs when the parathyroid glands are damaged either due to surgery or a disorder and are not able to produce enough PTH. Not having enough PTH can interfere with important functions of certain organs within the body. In some patients, doctors are not able to tell the cause of the disorder.

### Before you start using NATPARA, tell your doctor about all 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 have had too much calcium in your blood
- Have or have had high blood levels of certain electrolytes (for example, alkaline phosphatase)
- Are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. It is not known if NATPARA will harm your unborn baby or if NATPARA passes into your breast milk. You and your doctor should decide if you will use NATPARA or breastfeed. You should not do both.

**Tell your doctor about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

NATPARA and other medicines may affect each other, causing side effects. Especially tell your doctor if you are taking medicines that contain digoxin, alendronate, calcium supplements, or food products that contain calcium or active vitamin D.

Know the medicines you take. Keep a list of them to show your doctor or pharmacist each time you get a new medicine.

 **Natpara**<sup>®</sup>  
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for Injection  
25 • 50 • 75 • 100 mcg per dose strength

## Important reminders for using NATPARA

- Follow the Instructions for Use **every time you mix your NATPARA medicine cartridge, prepare your Q-Cliq™ pen, or give an injection** so you do not forget to do a step.
- Use these instructions exactly as shown.
- Read the Medication Guide that comes with NATPARA medicine cartridges.
- Do not use your Q-Cliq pen until a healthcare provider has shown you how to use it.
- Do not share your Q-Cliq pen or needles with anyone else.
- All NATPARA medicine cartridges, mixed and unmixed, **must** be stored in the refrigerator. Do not freeze.
- **Keep your NATPARA out of reach of children.**

### Your doctor will need to monitor how NATPARA is working

It is important to have routine blood tests and a yearly or twice yearly 24-hour urine collection test once the maintenance dose is achieved, so that your doctor can measure your calcium level and see how well you are responding to NATPARA.



Check with your doctor to get your routine tests

## Important Safety Information

### What is the most important information I should know about NATPARA? (cont'd)

**NATPARA may cause other serious side effects, including:** (cont'd)

#### 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 should I tell my healthcare provider before using NATPARA?

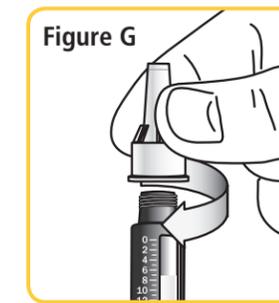
- **Before you start using NATPARA, tell your doctor about all of your medical conditions. Tell your doctor about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Please see Important Safety Information throughout.

Please click here for [Full Prescribing Information](#), [Medication Guide](#), and [Instructions for Use](#) for NATPARA.

## Important Reminders and Explanations for the Use of NATPARA Devices

### Preparing and Mixing Your NATPARA



#### Proper attachment of the needle before mixing

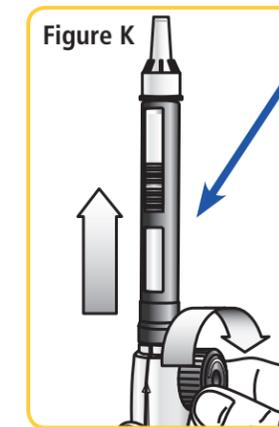
While keeping the needle cap straight, screw it firmly onto the cartridge in a clockwise direction. **Do not** remove the needle cap or guard until you are ready to give your medicine. (See Step 7 in the full Instructions for Use.)

#### Why is this important?

It is important to attach the needle properly to ensure that the needle pierces the drug medication cartridge (septum). This attachment is very important for both the mixing process, to allow air to vent out, as well as the Q-Cliq pen injector dosing process.

### Keep the Needle Pointing Up During Mixing

It is very important for the needle to be pointed up during mixing to enable a small amount of air to vent during the mixing process. If the needle is not pointed straight up during the mixing process, it is possible for some medication to leak out and to lose a dose or more.

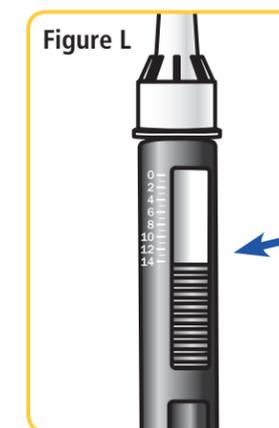


#### Proper use of the mixing device

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 Step 10 in the full Instructions for Use.)

#### Why is this important?

It is important to turn the knob of the mixing device slowly to prevent bubbling in the medication cartridge and to prevent leakage.



#### The stoppers inside the medication cartridge need to come together after mixing

Make sure the stoppers look like this and the stoppers stay together. (See Step 11 in the full Instructions for Use.)

#### Why is this important?

It is important to check that the stoppers inside the medication cartridge come together and touch to ensure that the mixing process is complete. It is important to check the stopper position after the plunger of the mixing device is fully extended. The position should be a little below but near the 14 Dose Indicator line and the medication liquid shouldn't be below the 0 Dose Indicator line.

## Important Reminders and Explanations for the Use of NATPARA Devices (cont'd)

### Preparing Your Q-Cliq™ Pen

#### The importance of proper priming of the pen

For instruction on how to prime your pen, please refer to the Instructions for Use (IFU) steps 22-26.

#### Why is this important?

**Proper priming is important to ensure proper dosage delivery using your Q-Cliq pen.**

Proper priming requires that the needle be pointed up during priming to enable a small amount of air to escape from the cartridge during the priming process. If the needle is not pointed straight up during the priming process it is possible for some medication to leak out, which could result in the loss of partial or full doses.

**Prime your Q-Cliq pen only one time for each new medicine cartridge.**

Priming your pen more than once for each new medicine cartridge may result in unintentional dispensing of medication, reducing the amount of medication in the cartridge. This may result in the loss of partial or full doses.

#### PLEASE NOTE:

- This brochure contains important information and explanations to remember while using NATPARA. **It does not replace the full Instructions for Use.**
- Follow the Instructions for Use **every time you mix your NATPARA medicine cartridge, prepare your Q-Cliq™ pen, or give an injection** so you do not forget to do a step.
- **Please see accompanying full Prescribing Information, including the Medication Guide and the Instructions for Use for NATPARA.** The Instructions for Use can be found online at [www.NATPARA.com](http://www.NATPARA.com) and are included with your NATPARA medicine.

## Important Safety Information

### What are the possible side effects of NATPARA?

- **NATPARA may cause serious side effects like allergic (hypersensitivity) reaction, including anaphylaxis.** Tell your healthcare provider or get emergency medical help right away if you have any of the following symptoms of an allergic reaction:
  - swelling of your face, lips, mouth, or tongue
  - breathing problems
  - fainting, dizziness, feeling lightheaded (low blood pressure)
  - fast heartbeat
  - itching
  - rash
  - hives
- **The most common side effects of NATPARA include:** tingling, tickling, or burning feeling of the skin, low or high blood calcium, headache, nausea, reduced sense of touch or sensation, diarrhea, vomiting, pain in joints, too much calcium in urine, and pain in limbs.

**These are not all the possible side effects of NATPARA. For more information, talk with your doctor.** You are encouraged to report negative side effects of prescription drugs to the FDA. Visit: [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call **1-800-FDA-1088**.

**Please see Important Safety Information throughout.**

**Please click here for Full Prescribing Information, Medication Guide, and Instructions for Use for NATPARA.**

## Important Reminders and Explanations for the Use of NATPARA Devices (cont'd)

### Giving Your Daily NATPARA

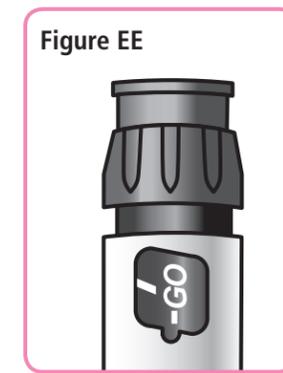


#### Proper attachment of the needle

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 Step 32 in the full Instructions for Use.)

#### Why is this important?

It is important to attach the needle properly to ensure that the needle pierces the drug medication cartridge (septum). This attachment is very important for both the mixing process, to allow air to vent out, as well as the Pen injector dosing process.



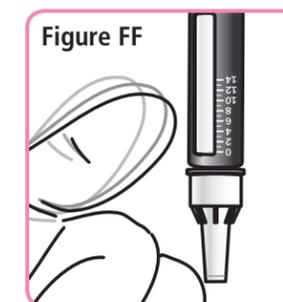
#### Turning dosage knob

Make sure the needle cap is pointing downward. Turn the dosage knob until “GO” lines up with the notch in the window. Do not turn the dosage knob past “GO.”

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. (See Step 36 in the full Instructions for Use.)

#### Why is this important?

It is important to turn the dosage knob exactly to “GO” – ensuring that “GO” lines up with the notch in the window. Not turning the pen exactly to “GO” could result in administering too little or too much medication.



#### Tapping the pen before administering

Make sure the needle cap is pointing downward. Gently tap the medicine cartridge **3 to 5** times. (See Step 37 in the full Instructions for Use.)

#### Why is this important?

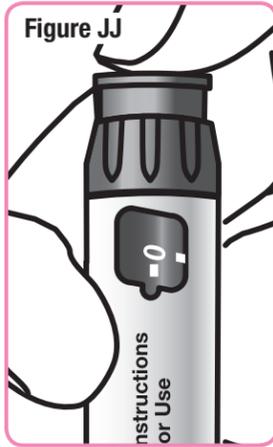
A small air bubble is normal within the properly mixed medication cartridge, therefore it is important to tap the pen prior to every dose so that the bubble doesn't get in the way of administering the proper dose.

Tapping moves any possible air bubble inside of the medicine cartridge away from the needle-end of the cartridge prior to injection. While tapping, it is important to keep the needle pointed downward to move any small air bubble away from the internal needle surface to ensure proper dosing of the medication liquid.

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## Important Reminders and Explanations for the Use of NATPARA Devices (cont'd)

### Giving Your Daily NATPARA (cont'd)



#### Giving the injection

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."

- 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.

(See Step 41 in the full Instructions for Use.)

#### Why is this important?

It is important to count slowly to 10 when administering the dose so that you avoid losing part of your dose.



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#### Warning: Possible bone cancer (osteosarcoma).

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#### NATPARA may cause other serious side effects, including:

##### 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.

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- 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.

## Who should not use NATPARA?

- **Do not use NATPARA** if you are allergic to parathyroid hormone or any of the ingredients in NATPARA.

## What should I tell my healthcare provider before using NATPARA?

- **Before you start using NATPARA, tell your doctor about all of your medical conditions. Tell your doctor about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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