

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

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.

How should I use NATPARA?

- Read the detailed **Instructions for Use** at the end of this Medication Guide.
- Use NATPARA exactly as your doctor tells you to.
- NATPARA is given with the Q-Cliq™ pen injector. Before you use NATPARA for the first time, a healthcare provider will show you how to use the Q-Cliq pen the right way and how to properly mix NATPARA using the mixing device.
- **Do not** stop taking or change your dose of NATPARA unless your doctor tells you to. Your calcium level could become dangerously low.
- Give NATPARA **1** time each day in your thigh just under your skin (subcutaneous).
- After you mix NATPARA, each medicine cartridge can be used for **14** injections (**14** doses). After you use the **14** doses throw away the cartridge.
- Do not throw away the Q-Cliq pen. It can be re-used for up to **2** years, by changing the mixed NATPARA medicine cartridges every 2 weeks (14 days).
- Look at NATPARA for any discoloration or particles in the medicine. It should be colorless. It is normal to see small particles in the liquid.
- Do not transfer the medicine from the NATPARA medicine cartridge to a syringe. This can cause you to use the wrong dose of NATPARA.
- Your doctor should check your blood calcium level when you start and while you are using NATPARA. After you start NATPARA, your doctor may change your doses of calcium and active vitamin D.
- 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.

What are the possible side effects of NATPARA?

NATPARA may cause serious side effects, including:

- See **“What is the most important information I should know about NATPARA?”**

The most common side effects of NATPARA include tingling, tickling, or a burning feeling of your skin (paresthesia), headache and nausea.

These are not all the possible side effects of NATPARA. For more information, ask your doctor. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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.**

General information about the safe and effective use of NATPARA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use NATPARA for a condition for which it was not prescribed. Do not give NATPARA to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about NATPARA. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about NATPARA that is written for health care professionals.

What are the ingredients in NATPARA?

Active ingredient: recombinant human parathyroid hormone

Inactive ingredients: sodium chloride, mannitol, citric acid monohydrate, m-cresol in sterile water

Manufactured by: NPS Pharmaceuticals, Inc., 550 Hills Drive, Bedminster, NJ 07921

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For more information, go to WWW.NATPARA.COM or call 1-855-628-7272.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: 12/2015