

**Appendix to DHPC: Patient/Caregiver Injection Instructions  
for Natpar 100 micrograms/dose shortage**

## **Background**

We previously advised of a shortage of Natpar 100micrograms/dose, from June 2022 for a period of at least six months. Due to unresolvable manufacturing challenges, Takeda will no longer be able to supply the Natpar 100 micrograms/dose strength and the dose strength will be unavailable on a permanent basis. This letter contains important information regarding how to handle the changes in the administration of Natpar due to the drug shortage of Natpar 100 micrograms/dose.

Your doctor will adjust your treatment in agreement with you. There are two alternative dosing options for substituting the Natpar 100 micrograms/dose injection:

### **1. If your doctor recommends two (2) consecutive Natpar 50 micrograms/dose injections:**

This information applies if you previously were prescribed Natpar 100 micrograms/day and your doctor has decided that you should receive two (2) consecutive injections of Natpar 50 micrograms/day from the same cartridge as a result of the drug shortage.

If you are prescribed two injections of Natpar 50 micrograms/dose per day by your doctor, a new cartridge will need to be prepared every 7 days.

The two (2) doses should be given from one cartridge within 15 minutes as follows:

1. Gather two disposable pen needles.
2. Ensure you have properly cleaned the surface with disinfectant/alcohol pads before you begin.
3. Follow the steps in the package leaflet to administer the first injection of Natpar 50 micrograms/dose in the left thigh. To minimize the risk of reactions at the site of injections, you should alternate between upper and lower parts of the thighs each day.
4. Remove the needle from the device, and discard in accordance with the instructions in the package leaflet.
5. Choose a second injection site on the right thigh, clean the site with an alcohol pad and let it dry. To minimize the risk of reactions at the site of injections, you should alternate between upper and lower parts of the thighs each day.
6. Follow the steps in the package leaflet again to perform another injection of Natpar 50 micrograms/dose, now in the right thigh, within 15 minutes of the first injection.
7. Remove the needle from the device, and discard in accordance with the instructions in the package leaflet
8. Check the cartridge dose indicator to confirm 2 doses of 50 micrograms/dose have been delivered from the cartridge

Note: To avoid the risk of infection, it is very important to clean the injection sites with alcohol pads and ensure the surface where the Natpar pen device is placed has been thoroughly cleaned. Remember to perform the second injection within 15 minutes at a new, cleaned injection site on the alternate thigh.

The package leaflet states that you should only take 1 dose of Natpar. However, since your doctor has prescribed two (2) injections of Natpar 50 micrograms/dose, you should take 2 doses. The second dose should be administered as soon as possible after the first, but no more than 15 minutes later.

You may have side effects related to low or high levels of calcium in your blood (see section on side effects). You may be given medicines to treat or help prevent these side effects, or you may be asked to stop some of the medicines you are taking. These medicines include calcium or vitamin D. If your symptoms are severe, your doctor may give you additional medical treatment. Your doctor may choose to monitor your calcium levels more closely.

If you are injecting two doses per day, you may experience more reactions in the injection site as each thigh is injected daily. You should decrease this risk by alternately injecting in the upper and lower part of the thighs. If you get any reactions at the injection site, please contact your doctor or pharmacist.

**If you forget a dose of Natpar.**

If you forget to use Natpar (or cannot inject it at your usual time), administer your injections as soon as you can but do not inject more than the prescribed number of doses in the same day.

Take your next dose of Natpar at the usual time the next day. You may need to take more calcium supplements if you have signs of low blood calcium; see section on side effects.

If you accidentally take only one dose of Natpar 50 micrograms/dose instead of 2 doses of Natpar 50 micrograms/dose, and more than 15 minutes has passed since the first dose, inject the second dose of Natpar 50 micrograms/dose in the other thigh as soon as possible. Contact your doctor or pharmacist and take two (2) doses of Natpar 50 micrograms/dose the next day as planned.

**If you take more Natpar than you should**

If you, by mistake, inject 3 or more doses of Natpar 50 micrograms/day in a day, contact your doctor or pharmacist immediately.

## **2. If your doctor recommends Natpar 75 micrograms/dose injection:**

This information applies if you were previously prescribed Natpar 100 micrograms/day and your doctor has decided that you should receive Natpar 75 micrograms/day as a result of the drug shortage. Since your dose of Natpar has been reduced, you are receiving less Natpar than you did before the drug shortage.

You may have side effects related to low or high levels of calcium in your blood (see section on side effects). You may be given medicines to treat or help prevent these side effects, or you may be asked to stop some of the medicines you are taking. These medicines include calcium or vitamin D. If your symptoms are severe, your doctor may give you additional medical treatment. Your doctor may choose to monitor your calcium levels more closely. Pay special attention to the symptoms associated with low levels of calcium since reduction in dose increases this risk.

If you are prescribed Natpar 75 micrograms/dose, follow the instructions for injection as described in the package leaflet.

## **This section applies to all patients:**

### **Possible side effects**

A change in your dosing can **increase the risk of high blood calcium and/or low blood calcium**.

Symptoms related to high or low calcium levels are included in the list below. If you experience any of these side effects, **contact your doctor right away**.

The following potentially serious side effects can occur when using Natpar:

- Very common: **high** levels of calcium in your blood, which can occur more often when you start treatment with Natpar.
- Very common: **low** levels of calcium in your blood; this can occur more often if you suddenly stop taking Natpar or in case of dose reduction.

Other side effects include:

### **Very common (may affect more than 1 in 10 people):**

- headaches\*,†
- tingling and numbness of the skin†
- diarrhea\*,†
- nausea and vomiting\*
- joint pain\*
- muscle spasms†

### **Common (may affect up to 1 in 10 people):**

- feeling nervous or anxious†
- sleep problems (feeling sleepy during the day or having trouble sleeping at night)\*
- fast or uneven heartbeat\*†
- high blood pressure\*
- cough†
- stomach pain\*
- muscle twitching or cramping†
- pain in your muscles†
- neck pain†
- pain in your arms and legs
- increased level of calcium in your urine\*
- need to pass urine often†
- fatigue and lack of energy\*
- chest pain
- redness and pain at injection site
- thirst\*
- antibodies (produced by your immune system) to Natpar
- in blood tests, your doctor may see decreased levels of vitamin D and magnesium†

**Not known (frequency cannot be estimated from the available data):**

- allergic reactions (hypersensitivity), such as: swelling of the face, lips, mouth, or tongue; shortness of breath; itching; rash; hives
- seizures (fits) due to low levels of calcium in your blood<sup>†</sup>

\*These side effects may be related to **high** levels of calcium in your blood.

<sup>†</sup>These side effects may be related to **low** levels of calcium in your blood.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system at <https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse>. By reporting side effects, you can help provide more information on the safety of this medicine.

**Questions**

If you have any questions regarding the use of Natpar, please contact the doctor who prescribed Natpar for you.