



This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of Precautions Teriparatide (genetical recombination)

January 11, 2018

Non-proprietary name

Teriparatide (genetical recombination)

Safety measure

Precautions should be revised in the package insert.

In the Important Precautions section, the following text should be added (underlined parts are revised):

Shock, loss of consciousness accompanying acute transient dropped blood pressure, seizures, or fall may occur from immediately after to several hours after administration of this drug. Some cases first occurred after more than several months of treatment. When this drug is administered, patients should be instructed to:

- 1) Keep as quiet as possible for approximately 30 minutes after administration.
- 2) Sit or lie down until they recover from the symptoms or signs if decreased blood pressure, dizziness, dizziness on standing up, palpitations, feeling poorly, nausea, facial pallor, or cold sweat occur after administration.



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In the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section with regard to shock and anaphylaxis, the following text should be revised (underlined parts are revised):

Anaphylaxis:

Anaphylaxis (dyspnoea, decreased blood pressure, rash etc.) may occur. Patients should be carefully monitored. If abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken.

Shock, loss of consciousness:

Shock, loss of consciousness accompanying acute transient dropped blood pressure may occur and cases that led to cardiac arrest, respiratory arrest have been reported. If abnormalities are observed, appropriate measures should be taken and discontinuing this drug should be considered from the next dose onward.