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

Summary of investigation results

Teriparatide preparations

January 11, 2018

Non-proprietary name

a. Teriparatide acetate
b. Teriparatide (genetical recombination)

Brand name (Marketing authorization holder)

a. Teribone 56.5 μg for subcutaneous injection (Asahi Kasei Pharma Corporation)
b. Forteo Subcutaneous Injection Kit 600 μg (Eli Lilly Japan K.K.)

Indications

a, b.
Osteoporosis with high risk of bone fracture

Summary of revision

a. 1. “Seizures” and “some cases first occurred after more than several months of treatment” should be added to the precaution with regards to acute transient dropped blood pressure, loss of consciousness, and fall in the Important Precautions section. The “acute transient dropped blood pressure, loss of consciousness” should be revised to “shock, loss of consciousness accompanying acute transient dropped blood pressure”.
b. 2. Precaution regarding “shock, loss of consciousness accompanying acute transient dropped blood pressure, seizures, and fall” should be added in the Important Precautions section.
a, b. 3. Description with regard to “shock, anaphylaxis” should be separated into “shock” and “anaphylaxis”. “Loss of consciousness” and the following text should be added to the description regarding “shock”.

Cases in which loss of consciousness accompanying acute transient dropped blood pressure led to cardiac arrest, respiratory arrest have been reported.

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Background of the revision and investigation results

Cases of cardiac arrest, respiratory arrest, and loss of consciousness have been reported in patients treated with teriparatide in Japan. Following investigation results based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 1 fiscal year in Japan

Cases associated with cardiac arrest and respiratory arrest

a. Teriparatide acetate

   A total of 2 cases associated with cardiac arrest and/or respiratory arrest have been reported (including 2 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.

b. Teriparatide (genetical recombination)

   A total of 1 case associated with cardiac arrest and/or respiratory arrest has been reported (including 0 cases for which a causal relationship to the product could not be ruled out). One fatality has been reported (including 0 cases for which a causal relationship to the product could not be ruled out).

Cases associated with loss of consciousness

a. Teriparatide acetate

   A total of 36 cases associated with loss of consciousness have been reported (including 35 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.

b. Teriparatide (genetical recombination)

   A total of 8 cases associated with loss of consciousness have been reported (including 5 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.

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