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Revision of Precautions
Teriparatide acetate
(subcutaneous injection)

January 11, 2018

Non-proprietary name

Teriparatide acetate

Safety measure

Precautions should be revised in the package insert.

In the Important Precautions section with regard to acute transient dropped blood pressure, loss of consciousness, and fall, the following text should be revised (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. Attention should be paid to the following points when this drug is administered.

1) Patients should be monitored for their condition for approximately 30 minutes as closely as possible following administration. Particularly when administering this drug to outpatients, it is desirable to confirm the patients' safety before letting them leave.
2) Patients should be instructed to 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.

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

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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:

Anaphylaxis:
Anaphylaxis 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 or respiratory arrest have been reported. If abnormalities are observed, appropriate measures should be taken and discontinuing administration should be considered from the next dose onward.

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E-mail: safety.info@pmda.go.jp