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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 Pentobarbital calcium

March 21, 2017

Non-proprietary name

Pentobarbital calcium

Safety measure

Precautions should be revised in the package insert.

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

Drug dependence may occur due to prolonged use. <u>Long-term use by chronic</u> <u>administration should be avoided. Therapeutic necessity should be carefully considered</u> <u>when continuing administration of this drug.</u>

In the Clinically Significant Adverse Reactions subsection regarding drug dependence of the Adverse Reactions section, the following text should be revised (underlined parts are revised):

Drug dependence: Drug dependence may occur due to prolonged use. Patients should be carefully monitored and <u>caution should be exercised for dosage and treatment duration</u> when administering this drug. Careful attention should be paid especially to patients with alcoholism, tendency to develop drug dependence or medical history of drug dependence, and serious neurosis.

* This drug is designated as a drug requiring preparation of a Drug Guide for Patients.

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