



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 Amobarbital

March 21, 2017

Non-proprietary name

Amobarbital

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):

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

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

Drug dependence: Drug dependence may occur due to prolonged use. Patients should be carefully monitored and caution should be exercised for dosage and treatment duration 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. In addition, withdrawal symptoms such as anxiety, insomnia, convulsions, nausea, hallucinations, delusion, excitation, confusion, or depressed state may occur due to rapid dose reduction or discontinuation of this drug during prolonged use. Discontinuation of administration should be carefully carried out such as by gradual dose reduction. Extra cautions should be exercised for elderly or frail patients.

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