



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 Fludiazepam

March 21, 2017

Non-proprietary name

Fludiazepam

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 regarding dependence of the Adverse Reactions section, the following text should be revised (underlined parts are revised):

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. In addition, withdrawal symptoms such as seizure, delirium, tremor, insomnia, anxiety, hallucination, or delusion 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.

The following text should be revised regarding irritable excitation and confusion:

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Irritable excitation, confusion, etc.: Irritable excitation or confusion, etc., may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken.

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

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