



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 Flunitrazepam (injections)

March 22, 2016

Non-proprietary name

Flunitrazepam (injections)

Safety measure

Precautions should be revised in the package insert.

In the Important Precautions section regarding depth of anesthesia, the following text should be revised (underlined parts are revised):

Depth of anesthesia and sedation should be limited to the minimum depth required for the management of surgery or laboratory test.

In the Important Precautions section regarding the preparation of equipment for artificial ventilation devices, the following text should be revised (underlined parts are revised):

Prior to administration of this drug, artificial ventilation devices such as oxygen inhalers, suction instruments, and trachea intubation sets as well as emergency analeptic drugs such as vasopressors should be prepared. In addition, flumazenil (benzodiazepine receptor antagonist) should be prepared as necessary.

In the Important Precautions section regarding observations of respiratory and cardiovascular functions, the following text should be revised (underlined parts are revised):

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Respiratory and cardiac function should be carefully monitored while being mindful of the respiratory tract during treatment with this drug. The patient's cardiorespiratory dynamics should be continuously monitored using devices such as a pulse oxymeter or sphygmomanometer.

In the Clinically significant adverse reaction subsection of the Adverse reaction section, the following text should be revised (underlined parts are revised):

Apnoea, respiratory depression, and glossoptosis:

Apnoea, respiratory depression, or glossoptosis may occur and may lead to serious outcomes. Patients should be carefully monitored. If these symptoms are observed, the airway should be opened and appropriate measures such as artificial respiration should be adopted.

Confusional state:

Confusional state may occur.