

Astellas Pharma: Approval of Additional Indication for Hypnosedative, Dormicum® in Japan

Tokyo, December 20, 2013 - [Astellas Pharma Inc.](#) (“Astellas”; Tokyo: 4503; President and CEO: Yoshihiko Hatanaka) announced the approval of an additional indication for hypnosedative, Dormicum® Injection 10 mg (generic name: midazolam) from the Ministry of Health, Labour and Welfare in Japan. The new indication is for use in sedation during surgery and procedures for dental, oral and maxillofacial care.

The application was submitted on February 20, 2013 based on published evidence from the "Handling of Ethical Drugs for Off-label Use", Notification No. 4 of the Research and Development Division / Notification No. 104 of the Evaluation and Licensing Division, dated February 1, 1999. Astellas expects that this approval will encourage the proper use of this product.

Product Overview

Product Name: Dormicum® Injection 10 mg

Generic Name: Midazolam

Indications: (The underlined part is the additional indication related to this approval.)

Anesthetic premedication

Introduction and maintenance of general anesthesia

Sedation during artificial respiration in critical care

Sedation during surgery and procedures for dental, oral and maxillofacial care

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