

Pharmaceuticals and Medical Devices Safety Information

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Executive Summary

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For full text version of Pharmaceuticals and Medical Devices Safety Information (PMDSI) No. 287, interested readers are advised to consult the PMDA website for upcoming information. The contents of this month's PMDSI are outlined below.

1. Lamotrigine-induced Severe Drug Eruption and Compliance with Dosage and Administration

A high incidence of skin disorders has been reported in cases where lamotrigine is administered at a dose exceeding the authorized dosage in the “Dosage and Administration” section. Strict adherence to “Dosage and Administration” has been requested; however, some cases of serious skin disorders involving noncompliance with “Dosage and Administration” have been reported. The reported cases of skin disorders and relevant safety measures are presented.

2. Fatal Fire Accidents Involving Patients during Use of Long-term Oxygen Therapy

Fatal fire accidents believed to be caused by smoking, etc. have occurred repeatedly in patients using long-term oxygen therapy. In 2011, 5 fatal fire accidents were reported. Healthcare professionals, patients, and their families are advised again not to smoke during long-term oxygen therapy and to keep the oxygen concentrator away from sources of fire, such as a heater.

3. List of Products Subject to Early Post-marketing Phase Vigilance (as of January 2012)

A list of products subject to Early Post-marketing Phase Vigilance as of January 1, 2012 will be provided in section 3 of the full text of PMDSI No.287.

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