

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. 319, interested readers are advised to consult the PMDA website for upcoming information. The contents of this month's PMDSI are outlined below.

1. Summary of the Relief System for Sufferers from Adverse Drug Reactions and the Cases of Non-payment of Relief Benefits Due to Improper Use of Drugs

Relief System for Sufferers from Adverse Drug Reactions will be summarized in section 1 of the full text to fully inform healthcare professionals of this system. In addition, relief benefit non-payment cases, for which there were no payments due to improper use of drugs, will be provided.

2. Revision of Precautions (No. 261)

Revision of Precautions for the following pharmaceutical:
Galantamine hydrobromide

3. List of Products Subject to Early Post-marketing Phase Vigilance

(as of December 2014)

A list of products subject to Early Post-marketing Phase Vigilance as of December 1, 2014 will be provided in section 3 of the full text.

(Reference) Handling of Fire during Long-term Oxygen Therapy

Fatal fire accidents caused by smoking, etc., have occurred repeatedly in patients using Long-term Oxygen Therapy (LTOT). Healthcare professionals, patients, and their families should be advised again not to smoke during LTOT and to keep the oxygen concentrator away from sources of fire, such as a heater.