

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

1. Review of Driving Precautions in Package Inserts of Ethical Drugs

The MHLW and PMDA are reviewing information described in package inserts of drugs for which disturbed consciousness and relevant adverse reactions are reported, focusing on alerts about potentially hazardous activities including driving. Section 1 of the full text will provide a background of the review and a summary of the Precautions revisions directed to the marketing authorization holders of the following drugs on November 26, 2013:

- Donepezil Hydrochloride
- Levofloxacin Hydrate (oral and injectable dosage form)
- Beraprost Sodium
- Azithromycin Hydrate (tablets for adults, dry syrup for adults, and injectable dosage form)
- Ofloxacin (oral dosage form)
- Garenoxacin Mesilate Hydrate
- Telaprevir
- Famciclovir
- Pilsicainide Hydrochloride Hydrate (oral dosage form)
- Propafenone Hydrochloride
- Bepidil Hydrochloride Hydrate
- Aciclovir (oral and injectable dosage form)
- Valaciclovir Hydrochloride

2. Important Safety Information

Regarding the revision of the Precautions section of package inserts of drugs in accordance with the Notification dated November 26, 2013, the contents of important revisions and case summaries that served as the basis for these revisions will be provided in section 2 of the full text.

1. Bosentan Hydrate

3. Revision of Precautions (No. 252)

Revisions of Precautions for the following pharmaceuticals:

1. Donepezil Hydrochloride
2. Pilsicainide Hydrochloride Hydrate (oral dosage form), Propafenone Hydrochloride, Bepidil Hydrochloride Hydrate
3. Furosemide
4. Beraprost Sodium, Azithromycin Hydrate (tablets for adults, dry syrup for adults, and injectable dosage form), Ofloxacin (oral dosage form), Garenoxacin Mesilate Hydrate, Levofloxacin Hydrate (injectable and oral dosage form), Telaprevir, Famciclovir
5. Clindamycin Hydrochloride, Clindamycin Phosphate (injectable dosage form)
6. Aciclovir (oral and injectable dosage form), Valaciclovir Hydrochloride

4. List of Products Subject to Early Post-marketing Phase Vigilance (as of December 2013)

A list of products subject to Early Post-marketing Phase Vigilance as of December 1, 2013 will be provided in section 4 of the full text.

Reference:

Fatal fire accidents caused by smoking, etc., have occurred repeatedly in patients using Long-term Oxygen Therapy (LTOT). Patients must not smoke tobacco products during usage of LTOT. Any sources of fire should not be placed near an oxygen concentrator. Healthcare professionals, patients and their caregivers should follow this advice.

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