

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

1. Systemic Allergy Associated with the Use of Quasi-drugs/Cosmetics

Cases of food-dependent exercise-induced allergies associated with transdermal or transmucosal sensitization to wheat, after using quasi-drugs/cosmetics containing hydrolyzed wheat powder have been reported. In these cases, the patients developed anaphylaxis after eating flour-containing foods followed by exercises. Case summaries of food-dependent exercise-induced allergy as well as its safety measures and diagnostic criteria provided by the Japanese Society of Allergology are presented. A planned study to investigate the details of reported cases is also introduced.

2. Important Safety Information

Regarding the revision of the Precautions section of package inserts of drugs in accordance with the Notification dated January 10, 2012, 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 of PMDSI No.288.

1. Daikenchuto

3. Revision of Precautions (No. 233)

Revisions of Precautions etc. for the following pharmaceuticals:

Galsulfase (Genetical Recombination), Aripiprazole, Haloperidol (injectable dosage form), Chloramphenicol (vaginal dosage form), Enoxaparin Sodium, Acarbose, Voglibose, Mitiglinide Calcium Hydrate/Voglibose, Miglitol, Tacrolimus Hydrate (oral and injectable dosage forms), Lenalidomide Hydrate, Saireito, Sitafloxacin Hydrate, Lopinavir/Ritonavir, Daikenchuto (Over-the-counter drug)

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

A list of products subject to Early Post-marketing Phase Vigilance as of February 1, 2012 will be provided in section 4 of the full text of PMDSI No.288.

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