

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

1. Safety Measures for Cervical Cancer Prevention Vaccines

Adverse reactions to cervical cancer prevention vaccines are reported to MHLW in accordance with the “Procedures for Urgent Vaccination Promotion,” irrespective of causality. These reactions are then discussed by an expert panel and information about the incidence is released to the public. Although an alert against common adverse reactions to cervical cancer prevention vaccines, such as syncope and vasovagal reaction, has been included in package inserts since the launch of the vaccines, many cases of syncope or vasovagal reaction have been reported, some of which resulted in secondary damage. Accordingly, MHLW will describe the information about the adverse reaction cases and safety measures in the full text. Healthcare professionals are requested to further exercise caution to prevent medication errors, because there have been reported cases where both 2-valent and 4-valent HPVs were used alternately by mistake.

2. Important Safety Information

Regarding the revision of the Precautions section of package inserts of drugs in accordance with the Notification dated April 24, 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.

1. Alogliptin Benzoate, Alogliptin Benzoate/Pioglitazone Hydrochloride, Sitagliptin Phosphate Hydrate, Vildagliptin, Linagliptin
2. Exenatide, Liraglutide (Genetical Recombination)
3. Mosapride Citrate Hydrate
4. Iodine

3. Revision of Precautions (No. 236)

Revisions of Precautions etc. for the following pharmaceuticals:

Ibuprofen (oral dosage form), Ibuprofen (suppository), Flurbiprofen (oral dosage form), Flurbiprofen Axetil, Canakinumab (Genetical Recombination), Lomefloxacin Hydrochloride (oral dosage form), Raltegravir Potassium, Acetaminophen, Isopropylantipyrine/Acetaminophen/Allylisopropylacetylurea/Anhydrous Caffeine, Tramadol Hydrochloride/Acetaminophen, Salicylamide/Acetaminophen/Anhydrous Caffeine/Chlorpheniramine Maleate (for adult), Salicylamide/Acetaminophen/Anhydrous Caffeine/Chlorpheniramine Maleate (for pediatric), Salicylamide/Acetaminophen/Anhydrous Caffeine/Promethazine Methylenedisalicylate (for adult), Salicylamide/Acetaminophen/Anhydrous Caffeine/Promethazine Methylenedisalicylate (for pediatric), Diprophylline/Dihydrocodeine Phosphate/*dl*-Methylephedrine Hydrochloride/Diphenhydramine Salicylate/Acetaminophen/Bromovalerylurea, Bendamustine Hydrochloride, Azacitidine, Sorafenib Tosilate, Pivmecillinam Hydrochloride, Cefcapene Pivoxil Hydrochloride Hydrate (tablet), Cefcapene Pivoxil Hydrochloride Hydrate (fine granules for periatric), Cefditoren Pivoxil (tablet), Cefditoren Pivoxil (fine granules for periatric), Cefteram Pivoxil (tablet), Cefteram Pivoxil (fine granules for periatric), Tebipenem Pivoxil, Moxifloxacin Hydrochloride (oral dosage form), Live Attenuated Human Rotavirus Vaccine, Oral, Rotavirus Vaccine, Live, Oral, Pentavalent, Products Containing Ibuprofen (over-the-counter drugs)

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

A list of products subject to Early Post-marketing Phase Vigilance as of June 1, 2012 will be provided in section 4 of the full text.

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