

Pharmaceuticals and Medical Devices Safety Information

No. 290 April 2012

Executive Summary

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For full text version of Pharmaceuticals and Medical Devices Safety Information (PMDSI) No. 290, interested readers are advised to consult the PMDA website for upcoming information. The contents of this month's PMDSI are outlined below.

1. Lookback study on Blood Products for Transfusion

A lookback study on blood products for transfusion is conducted to minimize the health hazards when blood products suspected of contamination by hepatitis viruses are identified.

The importance of the survey is presented with specific cases. Healthcare professionals are encouraged to cooperate with this survey.

2. Drug-induced Serious Skin Disorders

It is well known that skin disorders occur as adverse drug reactions. Serious skin disorders include Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN). Overview of the cases of SJS and TEN reported up to January 31, 2012 are presented.

3. Important Safety Information

Regarding the revision of the Precautions section of package inserts of drugs in accordance with the Notification dated March 19, 2012, the contents of important revisions and case summaries that served as the basis for these revisions will be provided in section 3 of the full text of PMDSI No.290.

1. Preparations Containing Acetaminophen

2. Cibenzoline Succinate
3. Triclofos Sodium, Chloral Hydrate
4. Metformin Hydrochloride (products with “Dosage and Administration” of maximum daily dosage of 2250 mg)

4. Revision of Precautions (No. 235)

Revisions of Precautions etc. for the following pharmaceuticals:

Pioglitazone Hydrochloride/Metformin Hydrochloride, Metformin Hydrochloride (products with “Dosage and Administration” of maximum daily dosage of 750 mg), Buformin Hydrochloride, Fingolimod Hydrochloride, Triazolam, Tramadol Hydrochloride, Tramadol Hydrochloride/Acetaminophen, Paliperidone, Risperidone, Blonanserin, Furosemide, Metenolone Enanthate, Metenolone Acetate, Mirabegron, Pyridoxal Phosphate Hydrate (injectable dosage form) (products containing benzyl alcohol as excipient), Pyridoxine Hydrochloride (injectable dosage form), Ribavirin (capsule), Interferon Beta (products for administration in combination with ribavirin), Iopamidol, Products Containing Acetaminophen (over-the-counter drugs)

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

A list of products subject to Early Post-marketing Phase Vigilance as of April 1, 2012 will be provided in section 5 of the full text of PMDSI No.290.

<Reference>

Increase of the Number of Cooperating Hospitals in the Project for “Japan Drug Information Institute in Pregnancy”

The MHLW established the Japan Drug Information Institute in Pregnancy in the National Center for Child Health and Development in October 2005 to provide consultation services and perform surveys. The system was strengthened in FY 2012 by getting the cooperation of three hospitals newly joined.

This English version of PMDSI is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail. The PMDA shall not be responsible for any consequence resulting from use of this English version.
