

Pharmaceuticals and Medical Devices Safety Information

No. 278 March 2011

Executive Summary

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Full text version of Pharmaceuticals and Medical Devices Safety Information (PMDSI) No. 278 will be upcoming soon. The contents of this month's PMDSI are outlined below.

1. Revision of Package Insert of Inferior Vena Cava Filter

The inferior vena cava (IVC) filter is a medical device to be placed in the IVC to prevent pulmonary embolism associated with deep venous thrombosis or other diseases. Filter migration and filter fracture associated with long-term use of IVC filters have been reported in Japan and overseas, and some of which led to filter embolization and/or IVC perforation.

The MHLW requires marketing authorization holders (MAHs) of these devices to revise the “Warnings” section in the package insert. The details are described in Section 1 of the Full text document.

2. Promotion of Safety Measures Using the PMDA medi-navi

“PMDA medi-navi (Pharmaceuticals and Medical Devices Information E-mail Alert Service)” is an information distribution service which informs the important safety information regarding pharmaceuticals and medical devices by e-mail when such information is issued. The use of PMDA medi-navi is encouraged to enhance safety measures. The details are described in Section 2 of the Full text document.

3. Important Safety Information

This section presents the contents of the revisions and case summaries that served as the basis for these revisions to important adverse reactions included under the Precautions section of package inserts of drugs that have been revised in accordance with the Notification dated February 15, 2011.

1. Isosorbide
2. Unseiin

4. Revision of Precautions (No. 224)

Revisions of Precautions for the following pharmaceuticals are included in Section 4 of the Full text document.

Gorinsan, San'oshashinto, Mesalazine (Tablet 250 mg, 500 mg, Granule, Enema), Mesalazine (Tablet 400 mg), Dried Thyroid, Liothyronine Sodium, Levothyroxine Sodium Hydrate, Goserelin Acetate, Oxybutynin Hydrochloride, Pirfenidone, Actinomycin D, Cisplatin (Excluding intra-arterial injection), Tamoxifen Citrate, Minocycline Hydrochloride, (Oral dosage form, Injectable dosage form), Prulifloxacin, Ribavirin (Capsule), Interferon Beta (for administration in combination with ribavirin), Unseiin (OTC drug), Gorinsan (OTC drug), San'oshashinto (OTC drug)

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

A list of products subject to Early Post-marketing Phase Vigilance as of March 1, 2011 is included in Section 5 of the Full text document.

PMDSI is also available on the Pharmaceuticals and Medical Devices Agency website (<http://www.pmda.go.jp/english/index.html>) and on the MHLW website (<http://www.mhlw.go.jp/>, Japanese only).

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.