



October 21, 2014

Notification

PFSB Notification No.1021-1

Director of Safety Division of Pharmaceutical and Food Safety Bureau
Ministry of Health, Labour and Welfare

Revision of Precautions of acetaminophen (for ethical use)

The Specified drug use-results survey on acetaminophen was conducted in accordance with the conditions for approval about the partial change in dosage and administration indicated for analgesia (maximum dose is now up to 1000 mg/dose and 4000 mg/day). The survey results were submitted to the Pharmaceuticals and Medical Devices Agency (PMDA) by the Marketing Authorisation Holder (MAH) of acetaminophen with partially changed dosage and administration. The PMDA reviewed the survey results and presented the review result in the Second Committee on New Drugs in the Pharmaceutical Affairs and Food Sanitation Council on September 5, 2014.

The present package insert of acetaminophen includes Warnings that concomitant use with other acetaminophen-combination products should be avoided. However, the Specified drug use-results survey revealed acetaminophen overdose cases due to concomitant use with other acetaminophen-combination products. Therefore the MHLW/PMDA concluded that Precautions should be revised, and to encourage further proper use of acetaminophen for ethical use in order to avoid concomitant use with other acetaminophen-combination products. You are encouraged to fully inform and instruct the relevant manufacturers to revise the package inserts in a timely manner and take necessary measures including providing information to healthcare providers.



Appendix

Non-proprietary Name

acetaminophen

Safety measure

Precautions should be revised in the package insert.

Information on concomitant use with other acetaminophen-combination products in Warnings section should be revised as follows:

Serious liver disorder due to acetaminophen overdose may occur in concomitant use of other acetaminophen-combination products (including OTC drugs). Concomitant use with other acetaminophen-combination products should be avoided. (See Important Precautions and Overdosage sections)

In Important Precautions section, the following texts should be added (underlined parts are revised):

Serious liver disorder due to acetaminophen overdose may occur in concomitant use of other acetaminophen-combination products (including OTC drugs). When other drugs are used concomitantly, especially when combination products such as common cold drugs and analgesics, anti-inflammatory agents are used concomitantly, healthcare professionals should check whether the concomitant drugs contain acetaminophen or not. Healthcare professionals should avoid concomitant use of acetaminophen-combination products with acetaminophen. In addition, patients should be educated to avoid concomitant use of acetaminophen-combination products with acetaminophen. (See Warnings and Overdosage sections)