



This English version 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.

Revision of Precautions Products containing pseudoephedrine hydrochloride or pseudoephedrine sulfate (OTC drugs)

April 21, 2016

Non-proprietary name

Products containing pseudoephedrine hydrochloride (OTC drugs)

Products containing pseudoephedrine sulfate (OTC drugs)

Safety measure

Precautions should be revised in the package insert.

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

If the following symptoms are observed after taking this drug, these may be adverse reactions, so immediately discontinue the use of this drug, and show this document to your physician, pharmacist, or registered salesperson for a consultation.

The following serious symptoms occur in rare cases. In such a case, immediately seek medical aid.

Acute generalised exanthematous pustulosis

Some symptoms, such as hyperthermia, widespread skin rash/redness, small pimples (small pustules) on reddened skin, general malaise, anorexia, may persist or suddenly worsen.