



# Summary of investigation results 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)

## **Brand name (Marketing authorization holder)**

New Long Acting S. Tac Nyscaps (Sato Yakuhin Kogyo Co., Ltd.), and the others

## **Indications\***

Alleviation of following symptoms associated with allergic rhinitis, acute rhinitis, or sinusitis:  
nasal discharge, nasal congestion, sneezing, watery eye, heaviness of head, and sore throat

## **Summary of revision**

“Acute generalised exanthematous pustulosis” should be added in the Consultation section.

## **Background of the revision and investigation results**

Acute generalised exanthematous pustulosis will be newly added in the package insert for the prescription product of pseudoephedrine hydrochloride. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that similar revisions of the package insert were necessary for the OTC drugs.



**The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan**

A total of 2 cases<sup>†</sup> associated with acute generalised exanthematous pustulosis have been reported (a causal relationship to the product could not be established for these patients). No fatality has been reported.

\* Pseudoephedrine hydrochloride or pseudoephedrine sulfate are contained in oral medicine for rhinitis, cold medicine. Indications of medicine for rhinitis present a representative sample of the indications.

† A combination products containing pseudoephedrine hydrochloride or pseudoephedrine sulfate with no description of acute generalised exanthematous pustulosis in the package insert.