



Summary of Investigation Results

Shosaikotokakikyosekko

May 13, 2021

Non-proprietary name

Shosaikotokakikyosekko

Branded name (Marketing authorization holder)

Tsumura Shosaikotokakikyosekko Extract Granules for Ethical Use (Tsumura & Co)

Indications

Relief of the following symptoms accompanied by painful swollen throat:

Tonsillitis and peritonsillitis

Summary of revisions

“Interstitial pneumonia” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of interstitial pneumonia have been reported in patients treated with shosaikotokakikyosekko in Japan. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

A total of 2 cases involving interstitial pneumonia have been reported to date (including 1 case for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities have been reported to date.



Pharmaceuticals and Medical Devices Agency

This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

Pharmaceuticals and Medical Devices Agency

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