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Translated by
Pharmaceuticals and Medical Devices Agency



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

Shosaikotokakikyosekko

May 13, 2021

Therapeutic category

Chinese medicines

Non-proprietary name

Shosaikotokakikyosekko

Safety measure

Precautions should be revised in the package insert.

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
Adverse Reactions Clinically Significant Adverse Reactions (N/A)	Adverse Reactions Clinically Significant Adverse Reactions <u>Interstitial pneumonia:</u> <u>If cough, dyspnoea, pyrexia, abnormal chest sound, etc. are observed, administration of this drug should be discontinued.</u> <u>Examinations such as chest X-ray and chest CT scan should be performed immediately, and administration of corticosteroids or other appropriate measures should be taken.</u>

N/A: Not Applicable. No corresponding language is included in the current package insert.

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