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.

Summary of investigation results

Sterile talc

August 6, 2015

Non-proprietary name

Sterile talc

Brand name (Marketing authorization holder)

Unitalc Intrapleural Suspensions 4 g (Nobelpharma Co., Ltd.)

Indications

Prevention of recurrent malignant pleural effusion

Summary of revision

1. “Patients with interstitial lung disease” should be newly added in the Careful administration section.
2. “Interstitial lung disease” should be newly added in the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of interstitial lung disease have been reported in patients treated with sterile talc in Japan. In addition, exacerbation of interstitial lung disease after the treatment with sterile talc has been reported in some patients who had the complication of interstitial lung disease prior to treatment. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

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

A total of 7 cases associated with interstitial lung disease have been reported (including 4 cases for which a causal relationship to the product could not be ruled out).

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Of the 7 cases, 4 fatal cases have been reported (a causal relationship between the product and the fatal outcome could be ruled out for these patients).

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