



Summary of investigation results

Sterile talc

March 20, 2018

Non-proprietary name

Sterile talc

Brand name (Marketing authorization holder)

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

Indications

Prevention of recurrent malignant pleural effusion

Summary of revision

“Shock, anaphylaxis” should be newly added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of shock or anaphylaxis have been reported in patients treated with sterile talc in Japan. Based on the results of their investigation of the evidence currently available and in consultation with expert advisors, MHLW/PMDA concluded that revision of the package insert was necessary.

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

A total of 3 cases associated with shock or anaphylaxis have been reported to date (although a causal relationship with the product could not be ruled out in these cases, the product was used for an unapproved indication in 1 case). No patient mortalities have been reported to date.