



Summary of investigation results

Pneumococcal vaccine

May 30, 2017

Non-proprietary name

Pneumococcal vaccine

Brand name (Marketing authorization holder)

Pneumovax NP (MSD K.K.)

Indications

Pneumococcal vaccine is indicated for the following individuals and patients aged 2 years or older at an increased risk for serious pneumococcal disease:

1. As prevention of pneumococcal infection in patients who have undergone splenectomy.
2. As prevention of pneumococcal infection in:
 - 1) Patients with splenic dysfunction caused by sickle cell disease or other conditions.
 - 2) Patients with an underlying disease such as chronic cardiac/respiratory disease, renal failure, hepatic dysfunction, diabetes mellitus, and chronic cerebrospinal fluid leakage.
 - 3) The elderly
 - 4) Patients with scheduled immunosuppressive therapy who have 14 days or more before the start of therapy.

Summary of revision

“Injection site necrosis, injection site ulcer” should be added in the Clinically Significant Adverse Reactions section with regard to “Cellulitis/cellulitis-like reaction”.

Background of the revision and investigation results

Cases of injection site necrosis or injection site ulcer have been reported in patients inoculated with pneumococcal vaccine in Japan. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded



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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 injection site necrosis or injection site ulcer have been reported (including 7 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.