



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 Pneumococcal vaccine

May 30, 2017

Non-proprietary name

Pneumococcal vaccine

Safety measure

Precautions should be revised in the package insert.

In the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section, the following text with regard to cellulitis/cellulitis-like reactions should be revised (underlined parts are revised):

Cellulitis/cellulitis-like reactions, injection site necrosis, injection site ulcer:

After vaccination, cellulitis/cellulitis-like reactions (e.g., redness, swelling, pain, and pyrexia) may occur primarily on injection site, resulting in necrosis or ulcer. If any of these conditions are observed, appropriate measures should be taken.