

Published by  
Ministry of Health, Labour and Welfare



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

## Influenza HA vaccine

May 9, 2019

### **Therapeutic category**

Vaccines

### **Non-proprietary name**

Influenza HA vaccine

### **Safety measure**

Precautions should be revised in the package insert.

**Pharmaceuticals and Medical Devices Agency**

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan  
E-mail: [safety.info@pmda.go.jp](mailto:safety.info@pmda.go.jp)

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  |
|--|---|
| <p>Adverse Reactions</p> <p>Clinically Significant Adverse Reactions</p> <p>Oculomucocutaneous syndrome (Stevens-Johnson syndrome):</p> <p>Oculomucocutaneous syndrome may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures should be taken.</p> | <p>Adverse Reactions</p> <p>Clinically Significant Adverse Reactions</p> <p>Oculomucocutaneous syndrome (Stevens-Johnson syndrome), <u>acute generalised exanthematous pustulosis</u>:</p> <p>Oculomucocutaneous syndrome <u>and acute generalised exanthematous pustulosis</u> may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures should be taken.</p> |

Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

| Current   | Revision   |
|---|--|
| <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Oculomucocutaneous syndrome (Stevens-Johnson syndrome)</p> | <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Oculomucocutaneous syndrome (Stevens-Johnson syndrome), <u>acute generalised exanthematous pustulosis</u></p> |

**Pharmaceuticals and Medical Devices Agency**

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan  
 E-mail: [safety.info@pmda.go.jp](mailto:safety.info@pmda.go.jp)