独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

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

Freeze-dried recombinant herpes zoster vaccine (prepared from Chinese hamster ovary cells)

October 22, 2025

Non-proprietary name

Freeze-dried recombinant herpes zoster vaccine (prepared from Chinese hamster ovary cells)

Brand name (marketing authorization holder)

Shingrix intramuscular injection (GlaxoSmithKline K.K.)

Japanese market launch

January 2020

Indications

Prevention of herpes zoster

Summary of revisions

"Guillain-Barre syndrome" has been added to the section "11.1 Clinically Significant Adverse Reactions" in "11. ADVERSE REACTIONS."

Investigation results and background of the revision

Cases involving Guillain-Barre syndrome were evaluated. Cases in which a causal relationship between this vaccine and Guillain-Barre syndrome was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

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Reference: Number of cases[*1] and patient mortalities involving Guillain-Barre syndrome reported in Japan and overseas

A total of 5 cases have been reported in Japan to date (including 1 case in which a causal relationship between the drug and the event was reasonably possible).
No patient mortalities have been reported in Japan to date.

A total of 11 cases have been reported overseas[*2] to date (including 4 cases in which a causal relationship between the drug and the event was reasonably possible).
No patient mortalities have been reported overseas to date.

[*1] Cases collected in the PMDA safety database for drugs

[*2] Cases in which the onset of Guillain-Barre syndrome due to vaccination with this vaccine is suspected, satisfying the following conditions:

- Cases reported under the PT "Guillain-Barre syndrome" that are assessed by the company as Brighton Criteria 1 to 3
- Cases in which this vaccine was reported as a suspected vaccine and considered evaluable by the company

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).