Safety Alert

November. 2026

Shingrix® (Recombinant Varicella Zoster Vaccine)- risk of Guillain-Barré syndrome (GBS)

EDA performs label update to include the following:

WARNINGS AND PRECAUTIONS :

An increased risk of Guillain-Barré syndrome has been observed following vaccination with SHINGRIX.

Adverse Reactions :

Guillain-Barré syndrome

System Organ Class: Nervous system disorders
Frequency: Very rare

Background:

Guillain-Barré Syndrome (GBS) is a rare, acute autoimmune disorder where the immune system attacks the peripheral nerves, damaging their protective myelin coating and blocking brain-to-body signals. It typically triggers days or weeks after a recent viral or bacterial infection, and very rarely follows surgery or vaccination. Because it can cause total paralysis within hours, GBS is a time-critical medical emergency.

Key Characteristics:

- **Ascending Weakness:** Symmetrical muscle weakness and tingling that starts in both legs and spreads up-ward.
- **Loss of Reflexes:** Early disappearance of deep tendon reflexes (like the knee-jerk).
- **Respiratory Distress:** Muscle failure that forces 20% to 30% of patients onto ventilators.
- **Autonomic Instability:** Dangerous, erratic fluctuations in blood pressure and heart rate.
- **Bulbar Weakness:** Rapidly developing difficulty with speaking, chewing, or swallowing.

Recommendations for Healthcare Professionals :

- **Awareness:** Recognize the very rare risk of Guillain-Barré syndrome (GBS) following Shingrix vaccination.
- **Patient Counseling:** Advise recipients to seek immediate medical care if they experience GBS symptoms (e.g., progressive weakness, limb tingling/numbness, difficulty walking, facial weakness, or trouble swallowing/ breathing).
- **Clinical Practice:** Continue administering Shingrix per approved indications, as the overall benefit-risk balance remains favorable.
- **Reporting:** Promptly report all suspected adverse drug reactions to the Egyptian Pharmacovigilance System.

Therapeutic Indications :

Shingrix is indicated for prevention of herpes zoster (HZ) and post- herpetic neuralgia (PHN) in:

- adults 50 years of age or older;
- adults 18 years of age or older at increased risk of **herpes zoster.**

Reference

TGA (click Here)