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IN BRIEF

Shingrix for Immunocompromised Adults

The FDA has licensed the adjuvanted, recombinant varicella zoster virus (VZV) vaccine *Shingrix* (GSK) for prevention of herpes zoster (shingles) in adults of any age who are or will be at elevated risk because of disease- or therapy-induced immunodeficiency or immunosuppression. *Shingrix* has been licensed for herpes zoster prevention in adults ≥50 years old since 2017.[1] It is the only VZV vaccine currently available in the US; *Zostavax*, a live-attenuated VZV vaccine, was withdrawn from the market in 2020.

FDA licensure of *Shingrix* for the new indication was based on the results of two studies: a randomized, placebo-controlled trial in 1846 immunocompromised adults ≥18 years old who had received an autologous hematopoietic stem cell transplant within the previous 50-70 days, and a post-hoc analysis of a similar trial in 569 adults who were receiving immunosuppressive therapy for hematologic malignancies. In both trials, *Shingrix* significantly decreased the incidence of herpes zoster occurring ≥1 month after the second dose compared to placebo (see Table 1).[2,3]

Table 1. Some *Shingrix* Clinical Trial Results

Treatment[1]	Herpes Zoster Incidence Rate[2]	Vaccine Efficacy
Trial 1 (auHSCT; n=1846)[3]		
Shingrix	30.0	68.2%
Placebo	94.3	
Trial 2 (hematologic malignancies; n=569)[4]		
Shingrix	8.5	87.2%
Placebo	66.2	

auHSCT = autologous hematopoietic stem cell transplant
1. Given as 2 doses IM 1-2 months apart.
2. Herpes zoster incidence per 1000 patient-years from 1 month after the second dose. Measured among patients who received both doses and did not develop herpes zoster before or <1 month after the second dose. The primary endpoint in trial 1 and a post-hoc endpoint in trial 2.
3. In immunocompromised adults who had undergone auHSCT 50-70 days before randomization. Median follow-up was 21 months. A Bastidas et al. JAMA 2019; 322:123.
4. In adults who were receiving immunosuppressive therapy for hematologic malignancies. Median follow-up was 13 months. AF Dagnew et al. Lancet Infect Dis 2019; 19:988.

Adverse effects of *Shingrix* in immunocompromised persons appear to be similar to those in healthy older adults. Myalgia, fatigue, headache, shivering, fever, GI symptoms, and injection-site pain, redness, and swelling are common. Severe local reactions preventing normal daily activities can occur.[1,4] In a postmarketing observational study in adults ≥65 years old, use of *Shingrix* was associated with an increased risk of Guillain-Barré syndrome in the 6 weeks after vaccination.[5]

In healthy older adults, *Shingrix* is typically given as two 0.5-mL doses administered intramuscularly 2-6 months apart. For immunocompromised patients who would benefit from a shorter vaccination schedule, the second dose can be given as early as 1 month after the first. Updated recommendations from the Advisory Committee on Immunization Practices (ACIP) on use of the vaccine in immunocompromised persons were not available at press time. ■

1. Shingrix – an adjuvanted, recombinant herpes zoster vaccine. Med Lett Drugs Ther 2017; 59:195.
2. A Bastidas et al. Effect of recombinant zoster vaccine on incidence of herpes zoster after autologous stem cell transplantation: a randomized clinical trial. JAMA 2019; 322:123.
3. AF Dagnew et al. Immunogenicity and safety of the adjuvanted recombinant zoster vaccine in adults with haematological malignancies: a phase 3, randomised, clinical trial and post-hoc efficacy analysis. Lancet Infect Dis 2019; 19:988.
4. M López-Fauqued et al. Safety profile of the adjuvanted recombinant zoster vaccine in immunocompromised populations: an overview of six trials. Drug Saf 2021; 44:811.
5. FDA Safety Communication. FDA requires a warning about Guillain-Barré Syndrome (GBS) be included in the prescribing information for Shingrix. March 24, 2021. Available at: https://bit.ly/3lmyvC6. Accessed August 3, 2021.

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