

SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted)

Media Factsheet

About Shingles and Its Impact

- Shingles, also known as herpes zoster, is caused by the reactivation of the varicella zoster virus (VZV), the same virus that causes chickenpox.¹
- Shingles typically presents as a painful, itchy rash that develops on one side of the body and can last for two to four weeks.^{2,3} Complications of shingles include postherpetic neuralgia (PHN), scarring, vision complications, secondary infection and nerve palsies.¹
- As we age, the cells in our immune system lose the ability to maintain a strong and effective response to VZV reactivation, such that after the age of 50 a person's risk for shingles increases.^{1,3}

About SHINGRIX

- SHINGRIX is a vaccine indicated for prevention of shingles (herpes zoster) in adults aged 50 years and older.⁴
- Weakened immunity in older adults presents a continuing challenge in adult vaccination.⁵
- SHINGRIX contains an antigen to trigger a targeted immune response, combined with an adjuvant intended to enhance this response.²
- Vaccines formulated with adjuvants have been shown to generate a stronger and longer immune response compared with non-adjuvanted vaccines.⁶
- SHINGRIX, a non-live vaccine, is the only shingles vaccine available formulated with an adjuvant.
- SHINGRIX was designed as a two-dose vaccine. The second dose should be administered two to six months after the first dose.⁴

SHINGRIX Important Safety Information

You should not receive SHINGRIX if you are allergic to any of its ingredients or had an allergic reaction to a previous dose of SHINGRIX. The most common side effects are pain, redness, and swelling at the injection site, muscle pain, tiredness, headache, shivering, fever, and upset stomach.

Vaccination with SHINGRIX may not protect all individuals.

Ask your healthcare provider about the risks and benefits of SHINGRIX. Only a healthcare provider can decide if SHINGRIX is right for you.

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Clinical Trial Results

- More than 38,000 people participated in the Phase III program to evaluate the efficacy, safety and immunogenicity of SHINGRIX.⁷
- In a pooled analysis of these studies, Shingrix demonstrated efficacy against shingles greater than 90% across all age groups, as well as sustained efficacy over a follow-up period of 4 years.^{2,8*}
- The most common side effects reported in the clinical trials were pain, redness and swelling at the injection site, muscle pain, tiredness, headache, shivering, fever, and upset stomach. Based on available data, the majority of reactions to the vaccine were transient and mild to moderate in intensity, lasting less than three days.^{2,8}
- In the pivotal Phase III trials, serious adverse events occurred at similar rates in the SHINGRIX and placebo groups. GSK is committed to the ongoing monitoring of its products.^{2,8}

*Against HZ incidence defined by new unilateral rash with pain that had no alternative diagnosis. 50-59 years: vaccine efficacy (VE) 96.6% (95% CI: 89.6-99.3); vaccinated N=3492, placebo N=3525 (ZOE-50). 60-69 years: VE 97.4% (95% CI: 90.1-99.7); vaccinated N=2141, placebo N=2166 (ZOE-50). 70-79 years: VE 91.3% (95% CI: 86.0-94.9); vaccinated N=6468, placebo N=6554 (pooled data from ZOE-50 and ZOE-70). ≥80 years: VE 91.4% (95% CI: 80.2-97.0); vaccinated N=1782, placebo N=1792 (pooled data from ZOE-50 and ZOE-70).

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4. SHINGRIX US Prescribing Information, October 2017.
5. Tseng H et al. Declining Effectiveness of Herpes Zoster Vaccine in Adults Aged ≥60 Years. *J Infect Dis*. 2016;213:1872-5.
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8. Cunningham H et al. Efficacy of the Herpes Zoster Subunit Vaccine in Adults 70 Years of Age or Older. *N Engl J Med*. 2016;375(11):1019-1032.