

# SHINGRIX:

THE FIRST NON-LIVE ADJUVANTED VACCINE TO HELP PROTECT AGAINST SHINGLES



## What is Shingles?

- Shingles, also known as herpes zoster, is caused by the reactivation of the varicella zoster virus (VZV), the same virus that causes chickenpox.<sup>1</sup>
- Shingles typically presents as a painful, itchy rash that develops on one side of the body and can last for two to four weeks.<sup>2,3</sup>
- As we age, the cells in our immune system lose the ability to mount a strong and effective response to infection, meaning that after the age of 50, a person's risk for shingles increases.<sup>1,3</sup>

## How SHINGRIX Works

- Weakened response to vaccines in older adults presents a continuing challenge in adult vaccination.<sup>4</sup>
- SHINGRIX contains an antigen that triggers a targeted immune response in the body to the vaccine, which helps the body build its own protection against shingles. When that is combined with an adjuvant, the body's response to the vaccine is improved.
- SHINGRIX, a non-live vaccine, is the only shingles vaccine available formulated with an adjuvant.
- SHINGRIX has been specifically formulated to address the age-related decline in immunity by helping your body build its own protection against shingles.<sup>5</sup>
- SHINGRIX was designed as a two-dose vaccine. The second dose should be administered two to six months after the first dose.<sup>6</sup>

## Clinical Trial Results

- More than 37,000 people participated in the Phase III program to evaluate the safety and efficacy of SHINGRIX.<sup>7</sup>
- In the pooled analysis of two separate Phase III studies, ZOE-50 and ZOE-70, SHINGRIX demonstrated efficacy against shingles above 90%, independent of age ( $\geq 50$ ,  $\geq 70$ ,  $\geq 80$  years of age) versus placebo.<sup>2,8\*</sup>
- Efficacy of SHINGRIX is maintained for four years post-vaccination and continues to be monitored.<sup>6</sup>
- The most common side effects reported in the clinical trials were pain, redness and swelling at the injection site, headache, stomach and digestive complaints, muscle pain, tiredness, chills and fever, injection site itching and generally feeling unwell. The majority of reactions to the vaccine were mild to moderate in intensity, lasting no more than three days.<sup>6</sup>

\* 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).  $\geq 80$  years: VE 91.4% (95% CI: 80.2-97.0); vaccinated N=1782, placebo N=1792 (pooled data from ZOE-50 and ZOE-70).



**SHINGRIX**  
HERPES ZOSTER VACCINE (NON-LIVE  
RECOMBINANT, AS01, ADJUVANTED)

### About Shingles

Shingles typically presents as a painful, itchy rash that develops on one side of the body, as a result of reactivation of latent chickenpox virus (VZV).<sup>2</sup> More than 90% of adults over 50 are infected with the virus.<sup>9</sup> Anyone who has been infected with VZV is at risk of developing shingles, with age and altered immune system being recognized as important risk factors.<sup>10</sup> The most common complication from shingles, occurring in up to 30% of shingles cases, is PHN, pain that lasts long after the rash and blisters heal.<sup>11</sup> Other complications can include scarring, vision complications, secondary infection and nerve palsies.<sup>10</sup>

### SHINGRIX Important Safety Information

SHINGRIX is a vaccine that helps protect adults 50 years of age and older against shingles (herpes zoster). 100% protection cannot be guaranteed. SHINGRIX is not for prevention of chickenpox or for the treatment of herpes zoster (HZ) or postherpetic neuralgia (PHN). SHINGRIX should not be used if you are allergic to any ingredient in the vaccine. Very common adverse events (>10% of doses) reported in clinical trials were pain, redness, and swelling at the injection site, headache, stomach and digestive complaints, muscle pain, tiredness, chills, and fever. Most side effects were mild or moderate, lasting less than three days. Ask your healthcare professional if SHINGRIX is right for you. Full product information can be found at <http://gsk.ca/shingrix/en>. To report an adverse event, please call 1-800-387-7374.

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1. Harpaz R, Ortega-Sanchez IR, Seward JF; Advisory Committee on Immunization Practices (ACIP), Centers for Disease Control and Prevention (CDC). Prevention of herpes zoster: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep* 2008 Jun;57(RR-5):1-30.
2. Lal H *et al*. Efficacy of an adjuvanted herpes zoster subunit vaccine in older adults. *N Engl J Med* 2015 May;372(22):2087-96.
3. Johnson RW *et al*. Herpes zoster epidemiology, management, and disease and economic burden in Europe: a multidisciplinary perspective. *Therapeutic Advances in Vaccines* 2015;3(4):109a-120.
4. Tseng H *et al*. Declining Effectiveness of Herpes Zoster Vaccine in Adults Aged  $\geq 60$  Years. *J Infect Dis* 2016;213:1872-5.
5. Chlibek R *et al*. Safety and immunogenicity of three different formulations of an adjuvanted varicella-zoster virus subunit candidate vaccine in older adults: a phase II, randomized, controlled study. *Vaccine* 2014 Mar;32(15):1745-53.
6. SHINGRIX Canada Product Monograph, March 2019.
7. GSK. Data on File. 2017.
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.
9. National Advisory Committee on Immunization. Statement on the Recommended use of Herpes Zoster Vaccine. January 2010, 36(ASC-1):1-19.
10. US Centers for Disease Control and Prevention. Shingles (Herpes Zoster): Overview. Available at: <https://www.cdc.gov/shingles/about/overview.html>. Last accessed: September 2017.
11. Kawai K, Gebremeskel BG, Acosta CJ. Systematic review of incidence and complications of herpes zoster: towards a global perspective. *BMJ Open* 2014 Jun;4(6):e004833.