

# Shingrix

(zoster vaccine recombinant, adjuvanted)



NEW PRODUCT SLIDESHOW

MPR

# Introduction

- **Brand name:** Shingrix
- **Generic name:** Zoster vaccine recombinant, adjuvanted
- **Pharmacological class:** Shingles vaccine
- **Strength and Formulation:** Susp for IM inj after reconstitution (contains 50mcg of recombinant glycoprotein E antigen, 50mcg of monophosphoryl lipid A, and 50mcg of QS-21); per 0.5mL; preservative-free

# Introduction

- **Manufacturer:** GlaxoSmithKline
- **How supplied:** Single-dose vials—1, 10 (antigen + adjuvant components)
- **Legal Classification:** Rx

# Shingrix



# Indications

- Prevention of herpes zoster (shingles) in adults  $\geq 50$  years of age
- **Limitations of use:** Not for preventing primary varicella infection (chickenpox)

# Dosage & Administration

- **<50yrs:** not recommended
- Give by **IM inj** in deltoid region of upper arm
- **≥50yrs:** one 0.5mL dose at Month 0 followed by second dose anytime between 2–6 months later
- Administer immediately upon reconstitution or store refrigerated and use within 6hrs

# Considerations for Special Populations

- **Pediatric:** <18 years: not established
- **Pregnancy:** Insufficient human data to establish vaccine-associated risk
- **Nursing mothers:** Data not available to assess effects on breastfed infant or milk production/excretion
- **Geriatric:** No clinically meaningful differences in efficacy across age groups or between older and younger subjects

# Contraindications

- History of severe allergic reaction to any component of the vaccine or after a previous dose of Shingrix



# Warnings/Precautions

- Review **immunization history** prior to administration
- Have appropriate medical treatment and supervision available to manage **allergic reactions**

# Interactions

- **Immunosuppressants** may reduce efficacy of Shingrix
- Concomitant **inactivated influenza vaccines**: see full labeling

# Adverse Reactions

- Local reactions (eg, pain, redness, swelling)
- Myalgia
- Fatigue
- Headache
- Shivering
- Fever
- GI symptoms

# Mechanism of Action

- Herpes zoster development increases with age and appears to be related to a decline in varicella zoster virus-specific immunity
- Shingrix was shown to **boost varicella zoster virus-specific immune response** and protect against zoster disease

# Clinical Studies

- **Study 1** was a randomized, placebo-controlled, observer-blind clinical study; randomization was stratified by age:
  - 50–59 years
  - 60–69 years
  - 70–79 years
  - $\geq 80$  years

# Clinical Studies

- Study patients were followed for the development of herpes zoster and postherpetic neuralgia for a median of 3.1 years
- Study patients received 2 doses of either **Shingrix** (n=7,344) or **placebo** (n=7,415)

# Clinical Studies

- Compared with placebo, Shingrix significantly reduced the risk of developing herpes zoster by **97.2%** (95% CI: 93.7, 99.0) in patients aged  $\geq 50$  years
  - 50–59 years: **96.6%** efficacy
  - 60–69 years: **97.4%** efficacy
  - $\geq 70$  years: **97.9%** efficacy
- No cases of postherpetic neuralgia were reported in the vaccine group vs. 18 in the placebo group

# Clinical Studies

- **Study 2** was a randomized, placebo-controlled, observer-blind study; randomization was stratified by age:
  - 70–79 years
  - $\geq 80$  years
- Study patients were followed for the development of herpes zoster and postherpetic neuralgia for a median of 3.9 years



# Clinical Studies

- Study patients aged  $\geq 70$  years received 2 doses of either Shingrix (n=6,541) or placebo (n=6,622)
- Compared with placebo, Shingrix significantly reduced the risk of developing herpes zoster by **89.8%** (95% CI: 84.3, 93.7) in patients aged  $\geq 70$  years
  - 70–79 years: **90.0%** efficacy
  - $\geq 80$  years: **89.1%** efficacy

# Clinical Studies

- 4 cases of postherpetic neuralgia were reported in the vaccine group vs. 28 cases in the placebo group
- Vaccine efficacy against **postherpetic neuralgia** was 85.5% (95% CI: 58.5, 96.3)
- The use of herpes zoster-associated **pain medications** was reported in fewer patients in the Shingrix group vs. placebo (43.5% vs. 71.7%)
- For more clinical trial data, see full labeling

# New Product Monograph

- For more information view the product monograph available at:

<http://www.empr.com/shingrix/drug/34761/>