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References

Recombinant zoster (shingles) vaccine: Drug information Lexicomp®

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(For additional information see "Recombinant zoster (shingles) vaccine: Patient drug information")

For abbreviations and symbols that may be used in Lexicomp (show table)

Brand Names: US

Shingrix

Pharmacologic Category

Vaccine; Vaccine, Recombinant

Dosing: Adult

Shingles prevention: Adults ≥50 years: IM: 0.5 mL administered as a 2-dose series at 0 and 2 to 6 months

CDC/ACIP recommendations: If the primary series is delayed or interrupted, the series does not need to be restarted. If the interval between dose 1 and 2 is <4 weeks, then the second dose should be repeated (CDC/ACIP [Dooling 2018]).

Dosing: Renal Impairment: Adult

There are no dosage adjustments provided in the manufacturer's labeling.

Dosing: Hepatic Impairment: Adult

There are no dosage adjustments provided in the manufacturer's labeling.

Dosing: Geriatric

Refer to adult dosing.

Dosage Forms

Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Suspension Reconstituted, Intramuscular:

Shingrix: 50 mcg [contains polysorbate 80]

Generic Equivalent Available (US)

No

Dosage Forms Considerations

Shingrix, a recombinant subunit vaccine, is supplied as a vial of lyophilized recombinant varicella zoster virus surface glycoprotein E antigen which is to be reconstituted with the accompanying vial of $AS01_B$ adjuvant suspension.

Medication Guide and/or Vaccine Information Statement (VIS)

In the US, the CDC-approved Vaccine Information Statement (VIS) is available at http://www.cdc.gov/vaccines/hcp/vis/vis-statements/shingles-recombinant.html.

Administration

IM: Administer IM, preferably in the deltoid muscle. Do not mix with other vaccines or injections; separate needles

and syringes should be used for each injection. Zoster vaccine (recombinant) should not be administered within 2 months of zoster vaccine (live) (CDC/ACIP [Dooling 2018]). To prevent syncope-related injuries, adolescents and adults should be vaccinated while seated or lying down (ACIP [Kroger 2017]). US law requires that the date of administration, the vaccine manufacturer, lot number of vaccine, and the administering person's name, title, and address be entered into the patient's permanent medical record.

For patients at risk of hemorrhage following intramuscular injection, the vaccine should be administered intramuscularly if, in the opinion of the physician familiar with the patient's bleeding risk, the vaccine can be administered by this route with reasonable safety. If the patient receives antihemophilia or other similar therapy, intramuscular vaccination can be scheduled shortly after such therapy is administered. A fine needle (23 gauge or smaller) can be used for the vaccination and firm pressure applied to the site (without rubbing) for at least 2 minutes. The patient should be instructed concerning the risk of hematoma from the injection. Patients on anticoagulant therapy should be considered to have the same bleeding risks and treated as those with clotting factor disorders (ACIP [Kroger 2017]).

Use

Herpes zoster prevention: Prevention of herpes zoster (shingles) in patients ≥50 years of age

The Advisory Committee on Immunization Practices (ACIP) recommends:

Routine vaccination of immunocompetent patients ≥50 years of age, including those who previously received varicella vaccine or zoster vaccine (live) or who report a previous episode of zoster; and patients with chronic medical conditions (eg, chronic renal failure, diabetes, rheumatoid arthritis, chronic pulmonary disease). Recombinant zoster vaccine is preferred over zoster vaccine (live) in immunocompetent patients (CDC/ACIP [Dooling 2018]).

Limitations of use: Not indicated for prevention of primary varicella infection (chickenpox) or for the treatment of zoster or postherpetic neuralgia (PHN) (CDC/ACIP [Dooling 2018]).

Medication Safety Issues

Look alike/Sound alike issues

Zoster Vaccine (Recombinant) may be confused with Zoster Vaccine (Live).

Shingrix (zoster vaccine [recombinant]) may be confused with Zostavax (zoster vaccine [live]).

RZV (zoster vaccine [recombinant]) may be confused with ZVL (zoster vaccine [live]).

RZV (zoster vaccine [recombinant]), ZVL (zoster vaccine [live]), or HZV (herpes zoster vaccine) may be confused with VAR (varicella vaccine).

Administration issues

Carefully review product labeling to ensure appropriate use of RZV (Shingrix) and ZVL (Zostavax); each vaccine has different components, routes of administration, dosage, and storage requirements.

Zoster vaccine (recombinant) contains recombinant varicella-zoster virus glycoprotein E (gE) antigen component with an adjuvant. Zoster vaccine live and and varicella vaccine live contain live, attenuated varicella-zoster viruses. Their indications, dosing, and composition are distinct. Zoster vaccines are indicated in older individuals to prevent reactivation of the virus that causes shingles, whereas varicella vaccine is indicated for the primary prevention of chickenpox. Zoster vaccines are not a substitute for varicella vaccine and should not be used in children.

Adverse Reactions

>10%:

Central nervous system: Fatigue (37% to 57%), headache (29% to 51%), shivering (20% to 36%)

Gastrointestinal: Gastrointestinal adverse effects (14% to 24%)

Local: Pain at injection site (69% to 88%), erythema at injection site (38% to 39%), swelling at injection site (23% to 31%)

Neuromuscular & skeletal: Myalgia (35% to 57%)

Miscellaneous: Fever (14% to 28%)

1% to 10%:

Central nervous system: Chills (4%), malaise (2%), dizziness (1%)

Dermatologic: Injection site pruritus (2%)

Gastrointestinal: Nausea (1%)

Neuromuscular & skeletal: Arthralgia (2%)

<1%, postmarketing, and/or case reports: Gout, high fever, lymphadenitis, optic neuropathy

Contraindications Severe hypersensitivity (eg, anaphylaxis) to recombinant zoster vaccine or any component of the formulation

Warnings/Precautions

Concerns related to adverse effects:

• Anaphylactoid/hypersensitivity reactions: Immediate treatment (including epinephrine 1 mg/mL) for anaphylactoid and/or hypersensitivity reactions should be available during vaccine use (ACIP [Kroger 2017]).

• Syncope: Syncope has been reported with use of injectable vaccines and may result in serious secondary injury (eg, skull fracture, cerebral hemorrhage); typically reported in adolescents and young adults and within 15 minutes after vaccination. Procedures should be in place to avoid injuries from falling and to restore cerebral perfusion if syncope occurs (ACIP [Kroger 2017]).

Disease-related concerns:

• Acute illness: The decision to administer or delay vaccination because of current or recent febrile illness depends on the severity of symptoms and the etiology of the disease. Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever) (ACIP [Kroger 2017]).

• Zoster infection: Not for use in the treatment of active zoster symptoms or postherpetic neuralgia. Vaccination with zoster vaccine (recombinant) should be delayed during an acute herpes zoster infection; may administer after acute illness is over and symptoms have resolved (CDC/ACIP [Dooling 2018]).

Concurrent drug therapy issues:

• Vaccines: Zoster vaccine (recombinant) should not be administered within 2 months of zoster vaccine (live) (CDC/ACIP [Dooling 2018]). In order to maximize vaccination rates, the ACIP recommends simultaneous administration (ie, >1 vaccine on the same day at different anatomic sites) of all age-appropriate vaccines (live or inactivated) for which a person is eligible at a single clinic visit, unless contraindications exist (ACIP [Kroger 2017]).

• Immunosuppressive agents: May reduce the effectiveness of the vaccine.

Special populations:

• Adults: Not for use in patients <50 years of age.

• Altered immunocompetence: Vaccination is recommended in patients receiving low-dose immunosuppressives (eg, <20 mg/day prednisone [or equivalent], inhaled or topical corticosteroids), patients anticipating immunosuppression or recovering from an immunocompromising condition (CDC/ACIP [Dooling 2018]).

• Pediatric: Zoster vaccine is not a substitute for varicella vaccine and should not be used in children and adolescents.

Other warnings/precautions:

• Effective immunity: Vaccination may not result in effective immunity in all patients. Response depends upon multiple factors (eg, type of vaccine, age of patient) and may be improved by administering the vaccine at the recommended dose, route, and interval. Vaccines may not be effective if administered during periods of altered immune competence (ACIP [Kroger 2017]).

Metabolism/Transport Effects

None known.

Drug Interactions

(For additional information: Launch drug interactions program) Lexicomp®

Belimumab: May diminish the therapeutic effect of Vaccines (Inactivated). Management: Patients should receive inactivated vaccines prior to initiation of belimumab therapy whenever possible, due to the risk for an impaired response to the vaccine during belimumab therapy. *Risk D: Consider therapy modification*

Fingolimod: May diminish the therapeutic effect of Vaccines (Inactivated). Management: Vaccine efficacy may be reduced. Complete all age-appropriate vaccinations at least 2 weeks prior to starting fingolimod. If vaccinated during fingolimod therapy, revaccinate 2 to 3 months after fingolimod discontinuation. *Risk D: Consider therapy modification*

Immunosuppressants: May diminish the therapeutic effect of Vaccines (Inactivated). Management: Vaccine efficacy may be reduced. Complete all age-appropriate vaccinations at least 2 weeks prior to starting an immunosuppressant. If vaccinated during immunosuppressant therapy, revaccinate at least 3 months after immunosuppressant discontinuation. **Exceptions:** Cytarabine (Liposomal). *Risk D: Consider therapy modification*

Venetoclax: May diminish the therapeutic effect of Vaccines (Inactivated). *Risk C: Monitor therapy*

Pregnancy Implications

Based on the lack of data in pregnant women, the ACIP recommends that consideration be given to delaying vaccination with zoster vaccine (recombinant) during pregnancy (CDC/ACIP [Dooling 2018]).

Breast-Feeding Considerations

It is not known if components of this vaccine are present in breast milk. In general, administration of recombinant vaccines does not affect the safety of breastfeeding for the mother or the infant (ACIP [Kroger 2017]). However, based on the lack of data in lactating women, the ACIP recommends that consideration be given to delaying vaccination with zoster vaccine (recombinant) to breastfeeding mothers (CDC/ACIP [Dooling 2018]). According to the manufacturer, the decision to breastfeed following immunization should consider the risk of infant exposure, the benefits of breastfeeding to the infant, and benefits to the mother.

Monitoring Parameters

Monitor for anaphylaxis and syncope for 15 minutes following administration (ACIP [Kroger 2017]). If seizure-like activity associated with syncope occurs, maintain patient in supine or Trendelenburg position to reestablish adequate cerebral perfusion.

Mechanism of Action

Stimulates active immunity to disease caused by the varicella-zoster virus thereby protecting again zoster disease

(shingles) and associated complications (eg, postherpetic neuralgia [PHN]).

Zoster vaccine (recombinant) reduced the incidence of zoster by ~97% in those 50 to <70 years of age and ~91% in those ≥70 years of age. Additional benefit was afforded to vaccine recipients who developed zoster by reduction in the incidence of PHN: ~89% for those ≥70 years.

Pharmacodynamics/Kinetics

Duration: ~85% to 93% vaccine efficacy after 4 years

Pricing: US

Suspension (reconstituted) (Shingrix Intramuscular)

50 mcg (per each): $168.00

Disclaimer: A representative AWP (Average Wholesale Price) price or price range is provided as reference price only. A range is provided when more than one manufacturer's AWP price is available and uses the low and high price reported by the manufacturers to determine the range. The pricing data should be used for benchmarking purposes only, and as such should not be used alone to set or adjudicate any prices for reimbursement or purchasing functions or considered to be an exact price for a single product and/or manufacturer. Medi-Span expressly disclaims all warranties of any kind or nature, whether express or implied, and assumes no liability with respect to accuracy of price or price range data published in its solutions. In no event shall Medi-Span be liable for special, indirect, incidental, or consequential damages arising from use of price or price range data. Pricing data is updated monthly.

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