

## VACCINE INFORMATION STATEMENT

# Recombinant Zoster (Shingles) Vaccine, RZV: What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See [www.immunize.org/vis](http://www.immunize.org/vis)

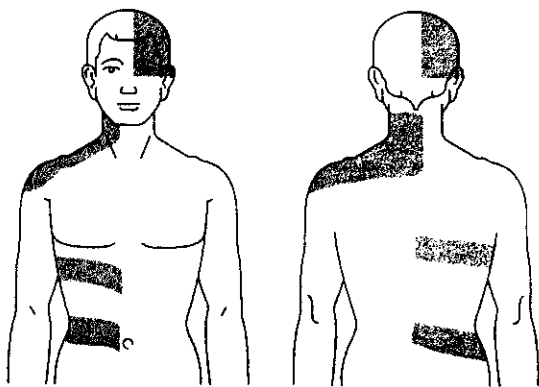
Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite [www.immunize.org/vis](http://www.immunize.org/vis)

### 1 Why get vaccinated?

**Shingles** (also called herpes zoster, or just zoster) is a painful skin rash, often with blisters. Shingles is caused by the varicella zoster virus, the same virus that causes chickenpox. After you have chickenpox, the virus stays in your body and can cause shingles later in life.

You can't catch shingles from another person. However, a person who has never had chickenpox (or chickenpox vaccine) could get chickenpox from someone with shingles.

A shingles rash usually appears on one side of the face or body and heals within 2 to 4 weeks. Its main symptom is pain, which can be severe. Other symptoms can include fever, headache, chills, and upset stomach. Very rarely, a shingles infection can lead to pneumonia, hearing problems, blindness, brain inflammation (encephalitis), or death.



For about 1 person in 5, severe pain can continue even long after the rash has cleared up. This long-lasting pain is called post-herpetic neuralgia (PHN).

Shingles is far more common in people 50 years of age and older than in younger people, and the risk increases with age. It is also more common in people whose immune system is weakened because of a disease such as cancer, or by drugs such as steroids or chemotherapy.

At least 1 million people a year in the United States get shingles.

### 2 Shingles vaccine (recombinant)

Recombinant shingles vaccine was approved by FDA in 2017 for the prevention of shingles. In clinical trials, it was more than 90% effective in preventing shingles. It can also reduce the likelihood of PHN.

Two doses, 2 to 6 months apart, are recommended for **adults 50 and older**.

This vaccine is also recommended for people who have already gotten the live shingles vaccine (Zostavax). There is no live virus in this vaccine.

### 3 Some people should not get this vaccine

Tell your vaccine provider if you:

- **Have any severe, life-threatening allergies.** A person who has ever had a life-threatening allergic reaction after a dose of recombinant shingles vaccine, or has a severe allergy to any component of this vaccine, may be advised not to be vaccinated. Ask your health care provider if you want information about vaccine components.
- **Are pregnant or breastfeeding.** There is not much information about use of recombinant shingles vaccine in pregnant or nursing women. Your healthcare provider might recommend delaying vaccination.
- **Are not feeling well.** If you have a mild illness, such as a cold, you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.



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Health and Human Services  
Centers for Disease  
Control and Prevention

## 4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of reactions.

After recombinant shingles vaccination, a person might experience:

- Pain, redness, soreness, or swelling at the site of the injection
- Headache, muscle aches, fever, shivering, fatigue

In clinical trials, most people got a sore arm with mild or moderate pain after vaccination, and some also had redness and swelling where they got the shot. Some people felt tired, had muscle pain, a headache, shivering, fever, stomach pain, or nausea. About 1 out of 6 people who got recombinant zoster vaccine experienced side effects that prevented them from doing regular activities. Symptoms went away on their own in about 2 to 3 days. Side effects were more common in younger people.

You should still get the second dose of recombinant zoster vaccine even if you had one of these reactions after the first dose.

### Other things that could happen after this vaccine:

- People sometimes faint after medical procedures, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting and injuries caused by a fall. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.
- Some people get shoulder pain that can be more severe and longer-lasting than routine soreness that can follow injections. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions to a vaccine are estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: [www.cdc.gov/vaccinesafety/](http://www.cdc.gov/vaccinesafety/)

## 5 What if there is a serious problem?

### What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a **severe allergic reaction** can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

### What should I do?

- If you think it is a **severe allergic reaction** or other emergency that can't wait, call 9-1-1 and get to the nearest hospital. Otherwise, call your health care provider.

Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at [www.vaers.hhs.gov](http://www.vaers.hhs.gov), or by calling 1-800-822-7967.

*VAERS does not give medical advice.*

## 6 How can I learn more?

- Ask your healthcare provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO) or
  - Visit CDC's website at [www.cdc.gov/vaccines](http://www.cdc.gov/vaccines)

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## Vaccine Information Statement Recombinant Zoster Vaccine

2/12/2018

Office use only





**Addendum to Recombinant Zoster (Shingles) Vaccine, RZV Vaccine Information Statement**

1. I agree that the person named below will get the vaccine checked below.
2. I received or was offered a copy of the Vaccine Information Statement (VIS) for the vaccine listed above.
3. I know the risks of the disease this vaccine prevents.
4. I know the benefits and risks of the vaccine.
5. I have had a chance to ask questions about the disease the vaccine prevents, the vaccine, and how the vaccine is given.
6. I know that the person named below will have the vaccine put in his/her body to prevent the disease this vaccine prevents.
7. I am an adult who can legally consent for the person named below to get the vaccine. I freely and voluntarily give my signed permission for this vaccine.

Vaccine to be given:  Recombinant Zoster (Shingles) Vaccine, RZV

Information about person to receive vaccine (Please print)				
Name: Last	First	Middle Initial	Birthdate (mm/dd/yy)	Sex (circle one)
				M F
Address: Street	City	County	State <b>TX</b>	Zip
Signature of person to receive vaccine or person authorized to make the request (parent or guardian):				
x _____			Date: _____	
x _____			Date: _____	
Witness				

**PRIVACY NOTIFICATION** - With few exceptions, you have the right to request and be informed about information that the State of Texas collects about you. You are entitled to receive and review the information upon request. You also have the right to ask the state agency to correct any information that is determined to be incorrect. See <http://www.dshs.texas.gov> for more information on Privacy Notification. (Reference: Government Code, Section 552.021, 552.023, 559.003, and 559.004)

**Privacy Notice:** I acknowledge that I have received a copy of my immunization provider's HIPAA Privacy Notice.

**For Clinic / Office Use Only**

Clinic / Office Address:	Date Vaccine Administered:
	Vaccine Manufacturer:
	Vaccine Lot Number:
	Site of Injection:
	Title of Vaccine Administrator:
	Signature of Vaccine Administrator:
	Date VIS Given:

**Notice:** Alterations or changes to this publication is prohibited without the express written consent of the Texas Department of State Health Services, Immunization Unit.

**Instructions: File this consent statement in the patient's chart.**