# SHINGLES VACCINE

### WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

#### What is shingles?

Shingles is a painful skin rash, often with blisters. It is also called Herpes Zoster.

A shingles rash usually appears on one side of the face or body and lasts from 2 to 4 weeks. Its main symptom is pain, which can be quite severe. Other symptoms of shingles 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 after the rash clears up. This is called **post-herpetic** neuralgia.

Shingles is caused by the

Varicella Zoster virus, the same virus that causes chickenpox. Only someone who has had a case of chickenpox – or gotten chickenpox vaccine – can get shingles. The virus stays in your body. It can reappear many years later to cause a case of shingles.

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

Shingles is far more common in people 50 and older than in younger people. It is also more

common in people whose immune systems are weakened because of a disease such as cancer, or drugs such as steroids or chemotherapy. At least 1 million people a year in the United States get shingles.

#### 2 Shingles vaccine

A vaccine for shingles was licensed in 2006. In clinical trials, the vaccine prevented shingles in about half of people 60 years of age and older. It can also reduce the pain associated with shingles.

A single dose of shingles vaccine is indicated for adults 60 years of age and older.

# 3 Some people should not get shingles vaccine or should wait

A person should not get shingles vaccine who:

- has ever had a life-threatening allergic reaction to gelatin, the antibiotic neomycin, or any other component of shingles vaccine. Tell your doctor if you have any severe allergies.
- has a weakened immune system because of
- HIV/AIDS or another disease that affects the immune system,
- treatment with drugs that affect the immune system, such as steroids,
- cancer treatment such as radiation or chemotherapy,
- a history of cancer affecting the bone marrow or lymphatic system, such as leukemia or lymphoma.
- has active, untreated tuberculosis.

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• is **pregnant**, or might be pregnant. Women should not become pregnant until at least three months after getting shingles vaccine.

Someone with a minor illness, such as a cold, may be vaccinated. But anyone who is moderately or severely ill should usually wait until they recover before getting the vaccine. This includes anyone with a temperature of 101.3°F or higher.

### 4

### What are the risks from shingles vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. However, the risk of a vaccine causing serious harm, or death, is extremely small.

No serious problems have been identified with shingles vaccine.

#### Mild Problems

- Redness, soreness, swelling, or itching at the site of the injection (about 1 person in 3).
- Headache (about 1 person in 70).

Like all vaccines, shingles vaccine is being closely monitored for unusual or severe problems.



## What if there is a moderate or severe reaction?

#### What should I look for?

• Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness. These usually occur within the first few hours after vaccination.

#### What should I do?

- Call a doctor, or get the person to a doctor right away.
- Tell your doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

#### 6 How can I learn more?

- Your provider 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)
- Visit CDC's website at www.cdc.gov/vaccines





DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Shingles Vaccine (9/11/06)

Vaccine Information Statement (Interim)



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#### Varicella-Zoster Vaccine

#### What are other names for this medicine?

Type of medicine: vaccine

Generic and brand names: varicella-zoster vaccine, injection; zoster vaccine live, injection; Zostavax

#### What is this medicine used for?

This medicine is a vaccine given by injection (a shot) to provide protection against herpes zoster (shingles). It is given to people over the age of 60.

#### What should my healthcare provider know before I take this medicine?

Before taking this medicine, tell your healthcare provider if you have ever had:

- · an allergic reaction to any medicine
- blood problems, leukemia, lymphoma, or any cancer affecting your bone marrow or lymph system, or if you
  receive blood transfusions or immune globulin
- a weakened immune system from diseases such as HIV or cancer or from taking immunosuppressant medicines to prevent organ transplant rejection or steroid medicines
- tuberculosis.

If you are severely ill at the time the shot is scheduled, wait until you recover before getting this vaccine. If you have a mild cold or mild upper respiratory infection with or without fever, you may still be able to get your shot. Talk to your healthcare provider about this.

Females of childbearing age: Talk with your healthcare provider if you are pregnant or plan to become pregnant. It is not known whether this medicine will harm an unborn baby. Do not become pregnant for at least 3 months after receiving this medicine. Do not breast-feed while taking this medicine without your healthcare provider's approval.

#### How do I use it?

This medicine is given by a healthcare provider.

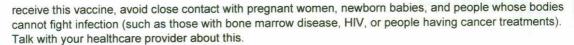
#### What should I watch out for?

This medicine may cause pain, tenderness, irritation, rash, or swelling on the skin where injections were given. The pain or tenderness should go away in a day or two.

Blood transfusions or immune globulin medicine can change the way this vaccine works. Talk with your healthcare provider about this.

After you receive this vaccine, you may be able to pass the virus to other people. If you get a rash after you

http://www.mdconsult.com/das/patient/body/87367199-5/0/10002/28278.html?preview=t&... 2/6/2008





#### What are the possible side effects?

Along with its needed effects, your medicine may cause some unwanted side effects. Some side effects may be very serious. Some side effects may go away as your body adjusts to the medicine. Tell your healthcare provider if you have any side effects that continue or get worse.

Life-threatening (Report these to your healthcare provider right away. If you cannot reach your healthcare provider right away, get emergency medical care or call 911 for help): Allergic reaction (hives; itching; rash; trouble breathing; tightness in your chest; swelling of your lips, tongue, and throat).

Serious (report these to your healthcare provider right away): High fever that continues or causes convulsions.

Other: Skin irritation or pain where injection is given, mild rash, cough, diarrhea, headache.

#### What products might interact with this medicine?

When you take this medicine with other medicines, it can change the way this or any of the other medicines work. Nonprescription medicines, vitamins, natural remedies, and certain foods may also interact. Using these products together might cause harmful side effects. Talk to your healthcare provider if you are taking:

- methotrexate (Rheumatrex Dose Pack)
- corticosteroids such as cortisone (Cortone), dexamethasone (Dexone, Dexameth), fludrocortisone (Florinef), hydrocortisone (Cortef), methylprednisolone (Medrol), prednisolone (Delta-Cortef, Prelone), prednisone (Orasone), and triamcinolone (Aristocort)
- immune globulin
- immunosuppressants such as azathioprine (Imuran), basiliximab (Simulect), cyclosporine (Sandimmune, Neoral), daclizumab (Zenapax), glatiramer (Copaxone), mycophenolate (CellCept), tacrolimus (Prograf), and sirolimus (Rapamune)
- medicines used to treat cancer such as cisplatin (Platinol), hydroxyurea (Hydrea), doxorubicin (Adriamycin, Rubex, Doxil), vinblastine (Velban, Alkaban-AQ), and vincristine (Oncovin, Vincasar)
- other live virus vaccines. Tell your healthcare provider about any other immunizations you have had or are scheduled to receive.
- radiation therapy.

Keep a record of all vaccines received and when you received them.

Keep a list of all your medicines (prescription, nonprescription, supplements, natural remedies, and vitamins) with you. Be sure that you tell all healthcare providers who treat you about all the products you are taking.

This advisory includes **selected information only** and may not include all side effects of this medicine or interactions with other medicines. Ask your healthcare provider or pharmacist for more information or if you have any questions.

Keep all medicines out of the reach of children.

Do not share medicines with other people.

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#### Special Instructions:

The herpes zoster virus vaccine is contraindicated in patients with a previous history of anaphylactic reaction following receipt of topical or systemic neomycin or gelatin. Patients with either severe neomycin hypersensitivity or gelatin hypersensitivity should not receive the vaccine. Neomycin allergy commonly manifests as a contact dermatitis, which is not a contraindication to receiving this vaccine. Immunization with the herpes zoster virus vaccine is contraindicated in any patient with a history of a serious allergic reaction, such as an anaphylactic reaction or angioedema, to any of the vaccine components. Each 0.65 ml dose contains 31.16 mg of sucrose, 15.58 mg of hydrolyzed porcine gelatin, 3.99 mg of sodium chloride, 0.62 mg of monosodium L-glutamate, 0.57 mg of sodium phosphate dibasic, 0.10 mg of potassium phosphate monobasic, 0.10 mg of potassium chloride, residual components of MRC-5 cells including DNA and protein, and trace quantities of neomycin and bovine calf serum.

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