

For Vaccination against Shingles (Herpes zoster, Zoster) – with Subunit Inactivated Vaccine (Recombinant)

Shingles (zoster) is a very painful and localised rash caused by the varicella-zoster virus – the same virus that is also the pathogen of chickenpox (varicella). Approximately 300,000 people in Germany fall ill with the virus each year – an upward trend.

Zoster only occurs in humans who have already had an earlier infection with chickenpox. The first contact in life with the varicella-zoster virus (VZV) causes chickenpox which in some cases can even go unnoticed. When chickenpox heals, some viruses remain in nerve centres (ganglia) of the spinal cord and brain. There they can survive a lifetime without causing symptoms of illness. With increasing age, particularly in those 50 years old and older, and in people with a weakened immune system (also due to medication), the viruses can once again become active. The reactivation of the VZV infection then causes the typical symptoms of zoster – discomfort, reddened skin, blistering on a confined area, in most cases severe pain. The truncus or the face are most often affected; usually only one half of the body or face. The name, shingles, stems from the affliction of nerves originating from the spine and radiating around half of the torso.

Shingles itself is not transmitted from human to human, however those with the illness can transmit the viruses to sensitive (non-immune) persons, e.g. from grandparents to grandchildren who then fall ill with chickenpox. The transmission can only occur through smear infection via the content of a blister and not through coughing or sneezing.

Shingles frequently occurs at an advanced age. There are initially blisters on the skin in the treated area of the affected nerves, which later dry up and become encrusted. The pain in the affected nerve region can persist for years (post-herpetic neuralgia). In addition to potential complications, such as paralyses or other bacterial infections in the skin areas affected by zoster, the seldom occurring inflammations of the spinal cord, cerebral membrane or brain are dreaded. If facial nerves are affected, inflammation of the eye involving the retina or the optic nerve, impairment of hearing or equilibrium or paralysis of the facial muscles may occur. In some cases, shingles can extend to adjacent nerve regions and very seldom throughout the entire body (herpes zoster generalisatus).

While there are medications that can accelerate the healing of symptoms of the skin, therapeutic options with respect to persistent nerve pain are limited. The shingles vaccine serves to protect against the zoster illness itself and against the occurrence of prolonged pain (post-herpetic neuralgia, PHN).

Vaccine

The inactivated zoster vaccine is produced using recombinant DNA technology. It contains a protein from the genetic material of the pathogen relevant for the immune response, which is bonded to an adjuvant. The vaccine is injected into the muscle (intramuscular injection), preferably on the upper arm. The inactivated vaccine against shingles is approved for persons 50 years old and older.

The vaccine can be administered simultaneously with an inactivated influenza vaccine, the 23-valent pneumococcal vaccine, as well as with the combination vaccine against tetanus, diphtheria, and pertussis on separate areas of the body (right and left upper arm). No empirical knowledge about the simultaneous administration with other vaccines is presently available.

Who should be vaccinated?

The Standing Committee on Vaccination (STIKO) recommends the vaccine

- As a standard vaccination for all persons 60 years old and older
- As well as for persons 50 years old and older with an increased health risk due to an underlying illness, e.g.:
- Patients with a congenital or acquired immune system disorder or one caused by medication
- HIV infection
- Rheumatoid arthritis or systemic lupus erythematoses
- Chronic inflammatory intestinal disorders
- Chronic kidney diseases
- Pulmonary diseases: COPD or asthma
- Diabetes mellitus.

The vaccine is administered twice at an interval of at least 2 months, although no later than 6 months. Immunisation is anticipated approx. 4 weeks after the second dose. Whether or not an additional dose is subsequently required after some years is not currently known.

Who should not be vaccinated?

In the event of an acute disease requiring treatment accompanied by a fever (over 38.5 °C), the vaccination should be postponed. Persons allergic to any ingredient of the vaccine should not be vaccinated. Your practitioner will inform you of exceptions.

There is no empirical knowledge surrounding the administration of the zoster vaccination in pregnant or nursing women, therefore the vaccination should be avoided as a precaution (the vaccine is only admissible for those 50 and older).

The vaccination is not recommended for persons, in whom shingles has already broken out. Treating an existing zoster-nerve inflammation is likewise not possible with the vaccination. However, it is possible that the vaccination can be administered at a later time. Your practitioner can advise you about this.

Behaviour following Vaccination

The person, who received the vaccination, does not require any special care; however, unusual physical stress should be avoided for 3 days after the vaccination. For persons, who are inclined to have cardiovascular reactions or in whom immediate allergies are known, the practitioner should be informed of this prior to the vaccination. Due to the occasional occurrence of fainting spells, the vaccination should potentially be administered in a reclined position.

Potential General and Local Reactions following Vaccination

In addition to the targeted immunity and thus the protection from the disease in vaccinated persons, temporary reddening or painful swelling and hardening as well as a warm sensation may occur quite frequently at the vaccination site following vaccinations (in ≥ 10 per cent of vaccinated persons). This is an expression of the normal interaction of the body with the vaccine. Itchiness may also occur at the vaccination site (approx. 1 to 20 per cent), occasionally (0.1 to 1 per cent) nearby lymph nodes will swell. Muscle and headaches, fatigue, chills, and fever as well as gastrointestinal symptoms (nausea and vomiting, abdominal pain) are very frequently described. Fever and chills can occur more frequently if the 23-valent pneumococcal vaccine is simultaneously administered. Joint pain occurs occasionally. Fainting spells occur occasionally immediately following (or even prior to) vaccination as a psychogenic reaction to the needle puncture, which can be temporarily accompanied by vision impairment, discomfort or involuntary movements during the recovery phase (see also under "Behaviour following Vaccination"). The specified reactions are usually temporary and subside again rapidly and without consequences.

Are vaccination complications possible?

Vaccination complications are very rare effects of the vaccination exceeding the normal extent of a vaccine reaction, which significantly affect the health condition of the vaccinated person. After administering the recombinant zoster vaccine, skin conditions were rarely observed in temporal conjunction with the vaccine as well as allergic reactions, primarily rash or hives. As with all other vaccinations, in rare cases an immediate allergic reaction and even shock cannot be precluded after administering this vaccine.

Consultation with the Vaccinating Practitioner regarding Potential Side Effects

In addition to this information sheet, your practitioner will offer you an information consultation. Should symptoms occur following a vaccination, which exceed the aforementioned quickly passing local and general reactions; the vaccinating practitioner is naturally available to you for consultation.

You can reach the vaccinating practitioner:

Declaration of Consent

For Providing the Shingles (Zoster) Vaccination – with Inactivated Vaccine

(Forms with a copy are also available to be able to provide a copy to persons receiving the vaccination or their parent/guardian in accordance with the Patient Rights Act.)

Name of the person receiving the vaccine _____

Date of birth _____

I have taken note of the content of the information sheet and have been informed of the vaccination in detail during a discussion with my practitioner.

- I have no further questions.
- I consent to the recommended shingles vaccination – with inactivated vaccine.
- I am refusing the vaccination. I have been informed of potential drawbacks of refusing this vaccination.

Notes: _____

Location, date: _____

Signature of the person receiving the vaccine.

Signature of the practitioner

Disclaimer

The original version (06/2018) of the information sheet was translated for the Robert Koch Institute courtesy of Das Deutsche Grüne Kreuz e.V. The German text is authoritative; no liability shall be assumed for any translation errors or for the relevance of the present translation in the case of a future revision of the German-language original.

Name

**Shingles vaccine
– with inactivated vaccine**

The following information is requested prior to providing the vaccine:

1. Is the person receiving the vaccine currently healthy?

- Yes No

2. Is the person receiving the vaccine aware of any allergies?

- Yes No

If yes, which _____

3. Did the person receiving the vaccine experience allergic symptoms, a high fever or other uncommon reactions following the previous vaccination?

- Yes No

If you would like to know more about the shingles vaccination, ask the vaccinating practitioner!

Please bring the vaccination passport to the vaccination appointment.