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**EPAR summary for the public**

# Zostavax

shingles (herpes zoster) vaccine (live)



This is a summary of the European public assessment report (EPAR) for Zostavax. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Zostavax.

## What is Zostavax?

Zostavax is a vaccine that is available as a powder and solvent to be made up into a solution for injection. The active substance is the attenuated (weakened) varicella-zoster virus.

## What is Zostavax used for?

Zostavax is used to vaccinate people aged 50 years or older, to prevent herpes zoster (also known as zoster or shingles) and the long-lasting nerve pain that may follow the disease (post-herpetic neuralgia).

The vaccine can only be obtained with a prescription.

## How is Zostavax used?

Zostavax is given as a single dose injected under the skin or into the muscle, preferably around the shoulder. In patients who have bleeding problems, the vaccine should be given under the skin.

## How does Zostavax work?

Herpes zoster, or shingles, is a disease caused by the reactivation of the varicella-zoster virus, the same virus that causes chickenpox. Shingles develops in people who have had chickenpox earlier in life, generally as a child. After chickenpox, the varicella-zoster virus stays in the body, in the nervous system, in a 'dormant' (inactive) state. Sometimes, after many years, and for reasons which are not fully understood, the virus becomes active again, and the patient develops shingles, a painful,

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blistering rash typically in one part of the body. The rash takes usually several weeks to clear, and may be followed by severe long-lasting pain (post-herpetic neuralgia) in the area where the rash was.

The risk of developing shingles increases with age and seems to be linked to a decline in immunity (protection) against varicella-zoster virus. Zostavax is a vaccine that was shown to 'boost' this immunity, protecting against shingles and the pain associated with it.

## How has Zostavax been studied?

The main study of Zostavax compared the vaccine with placebo (a dummy) vaccine in around 39,000 patients aged between 59 and 99 years. The study was a double-blind trial, which means that neither the doctor nor the patient knew what treatment the patient was receiving. The patients were followed for 2 to 4.5 years after vaccination. The main measure of effectiveness was based on the number of people who developed shingles and post-herpetic pain.

Two further studies looked at Zostavax in over 1,000 patients aged 50 years or older, of whom 389 were between 50 and 59 years of age. The studies looked at the ability of the vaccine to stimulate the production of antibodies against varicella-zoster virus in the blood, four weeks after injection.

## What benefit has Zostavax shown during the studies?

Zostavax was more effective than placebo in preventing shingles. Fewer people developed shingles after vaccination with Zostavax than placebo: 315 of the 19,254 patients who received Zostavax had shingles during the study, compared with 642 of the 19,247 who received placebo. Zostavax was also more effective than placebo in preventing post-herpetic neuralgia: 27 of the Zostavax patients had post-herpetic neuralgia, compared with 80 in the placebo group.

The additional two studies showed that patients vaccinated with Zostavax had blood levels of antibodies against varicella-zoster virus that were about two to three times higher four weeks after vaccination. The effect was seen both in patients aged between 50 and 59 years and in those aged 60 years and older.

## What is the risk associated with Zostavax?

In studies, the most common side effects with Zostavax are reactions at the site of the injection (redness, pain, swelling, itching, warmth and bruising), headache and pain in the arm or leg. Most of these side effects were mild. For the full list of all side effects reported with Zostavax, see the package leaflet.

Zostavax must not be used in people who are hypersensitive (allergic) to any of the components of the vaccine, or to any substances found at trace (very low) levels in the vaccine such as neomycin (an antibiotic). The vaccine must not be used in people who have problems with their immune system, either because they have a disease such as leukaemia, lymphoma, acquired immune deficiency syndrome (AIDS), or because they are taking medicines that affect the immune system. It must also not be used in patients with active untreated tuberculosis or in pregnant women. For the full list of restrictions, see the package leaflet.

## Why has Zostavax been approved?

The CHMP decided that Zostavax's benefits are greater than its risks and recommended that it be given marketing authorisation.

## What measures are being taken to ensure the safe and effective use of Zostavax?

A risk management plan has been developed to ensure that Zostavax is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Zostavax, including the appropriate precautions to be followed by healthcare professionals and patients.

## Other information about Zostavax

The European Commission granted a marketing authorisation valid throughout the European Union for Zostavax on 19 May 2006.

The full EPAR for Zostavax is available on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Zostavax, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2015.