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Shingrix® (active substance: varicella zoster virus glycoprotein E antigen)

First authorisation in Switzerland: 7 October 2021

Medicinal product (vaccine) for the prevention of shingles (herpes zoster) in adults

About the medicinal product

The medicinal product Shingrix, containing the active substance varicella zoster virus glycoprotein E antigen, consists of a powder with the active substance and a suspension for the preparation of a suspension for injection.

Shingrix is a vaccine used for preventing shingles (herpes zoster) in adults aged 50 and older, and in adults aged 18 and older who are at increased risk of contracting herpes zoster.

Shingles is an infectious disease caused by the varicella zoster virus. The varicella zoster virus is responsible for the outbreak of the highly infectious illness chickenpox. After an episode of chickenpox, the virus remains unnoticed in the body (in nerve cells) for life and can subsequently trigger shingles, which manifests itself as a strip of rash with blisters on one side of the body. Occasionally, the rash is accompanied by severe, prolonged pain.

Particularly in elderly individuals with a weakened immune system, shingles can cause severe symptoms and lead to complications.

Each year in Switzerland, herpes zoster is associated with over 20,000 consultations with a doctor. Half of the patients are older than 65.

Mode of action

The vaccine Shingrix causes the immune system of those who already possess immunity to the varicella zoster virus to produce specific antibodies and defence cells against the virus. As a result, the body's own defences are better equipped to fight the virus and prevent shingles.

Use

Shingrix, with the active substance varicella zoster virus glycoprotein E[1] antigen, is a prescription-only medicine.

Shingrix is available as a powder and suspension for the preparation of a suspension for injection. After reconstitution (preparation of the suspension for injection), a dose (0.5 ml) contains 50 micrograms of varicella zoster virus glycoprotein E.

Shingrix should be used in accordance with the official vaccination recommendations.

The primary vaccination schedule consists of two doses of 0.5 ml each: an initial dose followed by a second dose 2 months later. If deemed necessary by the doctor, the second dose can be administered up to 6 months later.

For individuals whose immune system is weakened or suppressed by an illness or a treatment and who would benefit from a shorter vaccination schedule, the doctor can administer the second dose as early as 1 to 2 months after the initial dose.

Shingrix is injected into a muscle, preferably the shoulder muscle.

In those who have previously been vaccinated with a live herpes zoster vaccine, Shingrix can be administered according to the same vaccination schedule described above.

Efficacy

In deciding whether to authorise the vaccine Shingrix, Swissmedic took into account the assessments of the European Medicines Agency (EMA), the US Food and Drug Administration (FDA) and the corresponding product information.

The review of efficacy by Swissmedic focused on subjects aged 18 and older with an increased risk of contracting herpes zoster, and patients over 18 who had received an autologous haematopoietic stem cell transplant (aHSCT).

The conducted studies demonstrated the efficacy of Shingrix in preventing herpes zoster compared to a dummy drug.

Precautions, undesirable effects & risks

Shingrix must not be used in those who are hypersensitive to the active substance or any of the excipients.

Like all vaccines, Shingrix can also produce side effects, although not necessarily in everyone. The most common adverse reactions are pain, redness or swelling at the injection site, tiredness, chills, fever, headache, gastrointestinal symptoms and muscle pain (myalgia).

As with other vaccines, for those who are suffering from an acute serious illness associated with a fever, the vaccination with Shingrix should be postponed to a later date. However, mild infections such as a cold should not lead to a postponement of the vaccination.

[1] Varicella zoster virus glycoprotein E, synthetically produced by (recombinant) DNA technology.

Like all vaccines, an anaphylactic reaction (acute allergic reaction) can occur following the administration of Shingrix. Therefore, the doctor should monitor patients after the vaccination and, if necessary, initiate medical measures.

All precautions, risks and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

The efficacy demonstrated in the conducted studies affords high protection against a herpes zoster infection, particularly in healthy subjects aged 50 and over.

Positive vaccine protection was also shown in those over 18 years of age who had received what is known as an autologous haematopoietic stem cell transplant (aHSCT). Further results from the studies supported the efficacy in adults with a weakened immune system who are at increased risk of contracting herpes zoster.

Taking all the risks and precautions into account, and based on the available data, the benefits of Shingrix outweigh the risks. Swissmedic has therefore authorised the vaccine Shingrix with the active substance varicella zoster virus glycoprotein E antigen for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Shingrix.

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.