

2. Varivax

Summary of product characteristics

4.4 Special warnings and precautions for use

Encephalitis

Encephalitis has been reported during post-marketing use of live attenuated varicella vaccines. In a few cases fatal outcomes have been observed, especially in patients who were immunocompromised (see section 4.3). Vaccinees/parents should be instructed to seek prompt medical attention if they/their child experience, after vaccination, symptoms suggestive of encephalitis such as loss or reduced levels of consciousness, convulsions or ataxia accompanied by fever and headache.

4.8 Undesirable effects

Post-Marketing Surveillance

Infections and infestations: Encephalitis*[†], Pharyngitis, Pneumonia*, Varicella (vaccine strain), Herpes zoster*[†], Aseptic meningitis[†]

* These selected adverse events reported with varicella vaccine (live) (Oka/Merck strain) are also a consequence of wild-type varicella infection. There is no indication of an increased risk of these adverse events following vaccination compared with wild-type disease from active post-marketing surveillance studies or passive post-marketing surveillance reporting (see section 5.1).

[†] See section c.

c. Description of selected adverse reactions

Complications associated with varicella

Complications of varicella from vaccine strain, including herpes zoster and disseminated disease such as aseptic meningitis and encephalitis, have been reported in immunocompromised and immunocompetent individuals. A few cases of encephalitis with a fatal outcome have been observed following vaccination with live attenuated varicella vaccines, especially in immunocompromised people (see section 4.4).

Package leaflet

4 Possible side effects

Side effects that have been reported during marketed use of VARIVAX include:

- Infection or inflammation of the brain (encephalitis) has been observed following vaccination with live attenuated varicella vaccines. In a few cases, this condition has been fatal, especially in people with weakened immune systems (as noted in section 2, Varivax must not be used in patients with weakened immune systems). Seek immediate medical attention if you or your child develop loss or reduced levels of consciousness, convulsions or loss of control of bodily movements, accompanied by fever and headache, as these might be a sign of infection or inflammation of the brain. Inform your doctor or pharmacist that you or your child received a live attenuated varicella vaccine.
- illnesses affecting the nervous system (brain and/or spinal cord) such as sagging facial muscles and drooping eyelid on one side of the face (Bell's palsy), walking unsteadily, dizziness, tingling or numbness of the hands and feet, ~~inflammation of the brain (encephalitis)~~, inflammation of the coverings of the brain and spinal cord not caused by bacterial infection (aseptic meningitis), fainting
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