VARIVAX PACKAGE INSERT ADVERSE REACTIONS

In clinical trials,[4].[5].[9]-'[5] VARI VAX was administered to 11,102 healthy children, adolescents, and adults. VARI VAX was generally well tolerated.

In a double-blind, placebo-controlled study among 914 healthy children and adolescents who were serologically confirmed to be susceptible to varicella, the only adverse reactions that occurred at a significantly ($p<0.05$) greater rate in vaccine recipients than in placebo recipients were pain and redness at the injection site.[4]

Children I to 12 Years of Age

In clinical trials involving healthy children monitored for up to 42 days after a single dose of VARI VAX, the frequency of fever, injection-site complaints, or rashes were reported as follows:

In addition, the most frequently (_1%) reported adverse experiences, without regard to causality, are listed in decreasing order of frequency: upper respiratory illness, cough, irritability/nervousness, fatigue, disturbed sleep, diarrhea, loss of appetite, vomiting, otitis, diaper rash/contact rash, headache, teething, malaise, abdominal pain, other rash, nausea, eye complaints, chills, lymphadenopathy, myalgia, lower respiratory illness, allergic reactions (including allergic rash, hives), stiff neck, heat rash/prickly heat, arthralgia, eczema/dry skin/dermatitis, constipation, itching.

Pneumonitis has been reported rarely (<1%) in children vaccinated with VARIVAX; a causal relationship has not been established.

Febrile seizures have occurred rarely (<0.1%) in children vaccinated with VARIVAX; a causal relationship has not been established.

Adolescents and Adults 13 Years of Age and Older

In clinical trials involving healthy adolescents and adults, the majority of whom received two doses of VARIVAX and were monitored for up to 42 days after any dose, the frequency of fever, injection-site complaints, or rashes were reported as follows:

In addition, the most frequently (_1%) reported adverse experiences, without regard to causality, are listed in decreasing order of frequency: upper respiratory illness, headache, fatigue, cough, myalgia, disturbed sleep, nausea, malaise, diarrhea, stiff neck, irritability/nervousness,

lymphadenopathy, chills, eye complaints, abdominal pain, loss of appetite, arthralgia, otitis, itching, vomiting, other rashes, constipation, lower respiratory illness, allergic reactions (including allergic rash, hives), contact rash, cold/canker sore.

As with any vaccine, there is the possibility that broad use of the vaccine could reveal adverse reactions not observed in clinical trials.

The following additional adverse reactions have been reported since the vaccine has been marketed:

Body As A Whole

Anaphylaxis in individuals with or without an allergic history.

Hemic and Lymphatic System

Thrombocytopenia.

Nervous/Psychiatric

Encephalitis; cerebrovascular accident; transverse myelitis; Guillain-Barré syndrome; Bell's palsy; ataxia; non-febrile seizures; dizziness; paresthesia.

Respiratory

Pharyngitis.

Skin

Stevens-Johnson syndrome; erythema multiforme; Henoch-Schänlein purpura; secondary bacterial infections of skin and soft tissue, including impetigo and cellulitis; herpes zoster.