For many patients...

**chickenpox.**

now avoidable...

VARIVAX®

[VARICELLA VIRUS VACCINE LIVE (Oka/Merck)]

now available.

Vaccination with VARIVAX may not result in protection of all healthy, susceptible children, adolescents, and adults. The duration of protection of VARIVAX is unknown at present and the need for booster doses is not defined. Please read the Brief Summary of the Prescribing Information on the last page of this advertisement. Before administering the vaccine, please read the full Prescribing Information for VARIVAX.
For many patients, VARIVAX® [Varicella Virus Vaccine Live (Oka/Merck)]:

**Efficacy**

The majority of vaccinees in clinical studies who were exposed to wild-type virus were either completely protected from chickenpox or developed a milder form of the disease.

In controlled clinical trials in children: Compared to historical controls...

<table>
<thead>
<tr>
<th>Single dose of VARIVAX in children</th>
<th>% difference from expected attack rates (natural exposure)</th>
<th>Breakthrough cases (vaccinees reporting chickenpox)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results with current vaccine using 2,900 PFU to 9,000 PFU (n=1,164)</td>
<td>A reduction of approximately 93%</td>
<td>0.2% to 1.0% per year (up to 3 years of follow-up)</td>
</tr>
<tr>
<td>In earlier trials with a vaccine using 1,000 PFU to 1,625 PFU (n=4,142)</td>
<td>A reduction of approximately 67% (57% to 77%)</td>
<td>2.1% to 3.6% per year (up to 6 years of follow-up)</td>
</tr>
</tbody>
</table>

PFU = plaque-forming units

**Immunogenicity**

In clinical trials, 1 dose maintained varicella antibodies in healthy children for at least 4 years.

<table>
<thead>
<tr>
<th>Years postvaccination</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>% vaccinees with detectable antibody level</td>
<td>98.8% (n=1,822)</td>
<td>98.9% (n=1,069)</td>
<td>97.5% (n=562)</td>
<td>99.5% (n=221)</td>
</tr>
</tbody>
</table>

A boost in antibody levels was observed in vaccinees following exposure to natural chickenpox, which could account for this apparent persistence of antibody levels. However, the duration of protection from varicella obtained using VARIVAX in the absence of wild-type boosting is unknown.

**In a placebo-controlled trial...**

One dose of VARIVAX (at a formulation containing 17,000 PFU) protected 96% to 100% of children over the first 2 years postvaccination.

- 100% calculated protection rate the first year: 0% contracted chickenpox with VARIVAX (n=491) compared to 8.5% with placebo (n=465).
- 96% calculated protection rate the second year (n=163 VARIVAX; n=161 placebo).

**Introducing new VARIVAX**

[VARICELLA VIRUS VACCINE LIVE (Oka/Merck)]

The First Vaccine Against Chickenpox Available In The U.S.
VARIVAX® [Varicella Virus Vaccine Live (Oka/Merck)]
generally well tolerated...

**Safety Profile**

In clinical trials of 11,102 children, adolescents, and adults (at formulations ranging from 1,000 to 17,000 PFU)

Frequency of fever, local reactions, or rashes (%) in healthy children, adolescents, and adults monitored for up to 42 days after any dose of VARIVAX

<table>
<thead>
<tr>
<th>Reaction (0-42 days)</th>
<th>CHILDREN after a single dose</th>
<th>ADOLESCENTS and ADULTS after first dose</th>
<th>ADOLESCENTS and ADULTS after second dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever (≥100°F [37.7°C] oral for adolescents and adults)</td>
<td>14.7% (n=8,827)</td>
<td>10.2% (n=1,584)</td>
<td>9.5% (n=956)</td>
</tr>
<tr>
<td>Injection-site complaints</td>
<td>19.3% (n=8,916)</td>
<td>24.4% (n=1,606)</td>
<td>32.5% (n=955)</td>
</tr>
<tr>
<td>Varicella-like rash (injection site)</td>
<td>3.4% (n=8,916)</td>
<td>3.0% (n=1,606)</td>
<td>1.0% (n=955)</td>
</tr>
<tr>
<td>Varicella-like rash (generalized)</td>
<td>3.8% (n=8,916)</td>
<td>5.5% (n=1,606)</td>
<td>0.9% (n=955)</td>
</tr>
</tbody>
</table>

- Vaccine recipients should avoid close association with susceptible high-risk individuals (e.g., newborns, pregnant women, and immunocompromised persons). The potential risk of transmission of vaccine virus should be weighed against the risk of transmission of natural varicella virus in such circumstances.

- In children and adults, adverse experiences reported at ≥1% frequency included (without regard to causality): upper respiratory illness, cough, irritability/somnolence, fatigue, disturbed sleep, diarrhea, loss of appetite, vomiting, otitis, rash, headache, teething, malaise, abdominal pain, nausea, eye complaints, chills, lymphadenopathy, myalgia, stiff neck, arthralgia, lower respiratory illness, allergic reactions, constipation, itching, and cold/canker sores. In children, pneumonitis and febrile seizures have been reported rarely; a causal relationship has not been established.

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

**With several benefits.**

**Helps prevent disease and work loss**
- Helps reduce costs of work time lost by family members who stay home to care for children with chickenpox.

**VARIVAX is indicated for vaccination against varicella in individuals 12 months of age or older**
- For children 12 months to 12 years of age: one 0.5 mL dose, administered subcutaneously.
- For individuals 13 years of age and older: two 0.5 mL doses, administered subcutaneously (second dose 4 to 8 weeks after initial dose).

**Introducing new VARIVAX**

**[VARICELLA VIRUS VACCINE LIVE (Oka/Merck)]**

The First Vaccine Against Chickenpox Available In The U.S.

For a Brief Summary of the Prescribing Information, please see the last page of this advertisement. Before administering the vaccine, please read the full Prescribing Information for VARIVAX.
Ordering/Storage

- Call 1-800-MERCK-RX (1-800-637-2579) to order VARIVAX.
- Call 1-800-9-VARIVAX (1-800-982-7482) if you have any questions about VARIVAX or would like to obtain materials and information for your patients and practice.
- Lyophilized VARIVAX is available in single-dose vials packaged in boxes of 1 or 10 vials with accompanying diluent.
- Store vaccine frozen at an average temperature of +5°F (-15°C) or colder until reconstitution. Store in a frost-free freezer with an average temperature of +5°F (-15°C) is acceptable.
- Store diluent separately at room temperature or in the refrigerator.

BRIEF SUMMARY

Please read the full Prescribing Information for complete details.

INDICATIONS AND USAGE

VARIVAX® [Varicella Virus Vaccine Live (Oka/Merck)] is indicated for vaccination against varicella in individuals 12 months of age and older.

Reconstitution

The duration of protection of VARIVAX is unknown at present and the need for booster doses is not defined. However, a boost in antibody levels has been observed in vaccinated following exposure to natural varicella as well as following a booster dose of VARIVAX administered four to six years post vaccination.

In a highly vaccinated population, immunity for some individuals may wane due to lack of exposure to natural varicella as a result of antibiotic prophylaxis. Post-marketing surveillance studies are ongoing to evaluate the need and timing for booster vaccination.

Vaccination with VARIVAX may not result in protection of all healthy susceptible children, adolescents, and adults (see CLINICAL PHARMACOLOGY section of the full Prescribing Information).

CONTRAINDICATIONS

A history of hypersensitivity to any component of the vaccine, excluding gelatin.

A history of anaphylactic reaction to neomycin (each dose of reconstituted vaccine contains trace quantities of neomycin).

Individuals with blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic system.

Individuals receiving immunosuppressive therapy.

Individuals who are an immunosuppressant drugs are more susceptible to infections due to individuals.

Vaccination with live attenuated varicella vaccine can result in a more extensive vaccine-associated rash or disseminated disease in individuals on immunosuppressant doses of corticosteroids.

Individuals with primary and acquired immunodeficiency states, including those who are immunosuppressed in association with AIDS or other conditions mandating infection with human immunodeficiency virus, cellular immune deficiencies, and hypogammaglobulinemia and hypogammaglobulinemic states.

A family history of congenital or hereditary immune deficiencies, unless the immune competence of the potential vaccine recipient is demonstrated.

Active untreated tuberculosis.

Any fatal respiratory illness or other active fatal infection.

Pregnancy: The possible effects of the vaccine on fetal development are unknown at this time. However, natural varicella is known to cause fetal harm. If exposure of pregnant females is undertaken, pregnancy should be avoided for 3 months following vaccination (see PRECAUTIONS, Pregnancy).

WARNINGS

Children and adolescents with acute lymphoblastic leukemia (ALL) in remission can receive the vaccine under an investigational protocol. More information is available through the VARIVAX Vac-var-actor Center, Bio- Pharm Clinical Services, Inc., 4 Valley Square, Blue Bell, PA 19422, (612) 293-0897.

PRECAUTIONS

General

Anaphylactic treatment, provisions, including epinephrine injection (1:1000), should be available for immediate use should an anaphylactic reaction occur.

The duration of protection from varicella infection after vaccination with VARIVAX is unknown.

It is not known whether VARIVAX given immediately after exposure to natural varicella virus will prevent illness.

Vaccination should be deferred for at least 5 months following blood or plasma transfusions or, administration of immune globulin or plasma zoster immune globulin (ZIG).

Following administration of VARIVAX, any immune globulin, including ZIG, should not be given for 2 months thereafter unless its use outweighs the benefit of vaccination.

Vaccine recipients should avoid use of salicylates for 6 weeks after vaccination with VARIVAX as Raye's syndrome has been reported following the use of salicylates during natural varicella infection.

Individuals vaccinated with VARIVAX may potentially be capable of transmitting the vaccine virus to close contacts. Therefore, vaccine recipients should avoid close contact with susceptible high-risk individuals (e.g., newborns; pregnant women; immunocompromised persons). The potential risk of transmission of vaccine virus should be weighed against the risk of dissemination of natural varicella in such circumstances.

The safety and efficacy of VARIVAX have not been established in children and young adults who are known to be infected with human immunodeficiency viruses but who do not have overt clinical manifestations of immunosuppression.

Care should be taken by the healthcare provider for safe and effective use of VARIVAX.

The healthcare provider should question the patient, parent, or guardian about reactions to a previous dose of VARIVAX or a similar product.

The healthcare provider should obtain the previous immunization history of the vaccinee. VARIVAX should not be injected into a blood vessel.

Vaccination should be deferred in patients with a family history of congenital or hereditary immunodeficiency until the patient's own immune system has been evaluated.

A separate sterile needle and syringe should be used for administration of each dose of VARIVAX to prevent transfer of infectious disease.

Needles should be disposed of properly and should not be recap.

Information for Patients

The healthcare provider should inform the patient, parent, or guardian of the benefits and risks of vaccination.

Patients, parents, or guardians should be instructed to report any adverse reactions to their healthcare provider.

Pregnancy should be avoided for 3 months following vaccination.

Drug Interactions

See PRECAUTIONS, General, regarding the administration of immune globulins, salicylates, and transfusions.

Use with Other Vaccines

Results from clinical studies indicate that VARIVAX can be administered concomitantly with M-M-PP (Measles, Mumps, and Rubella Virus Vaccine Live, MMR), Measles vaccine, Varicella vaccine, DTP, Hb (Hemophilus b Conjugate Vaccine, Merck), and OPV (Poliovirus Type 1, 2, and 3 Sabin Attenuated, Live Virus Vaccine)

Limited data from an experimental product containing varicella vaccine suggest that VARIVAX can be administered simultaneously with DTP (diphtheria, tetanus, acellular pertussis) and Pedipvax® (Haemophilus b Conjugate Vaccine, Merck) using separate sites and syringes (see CLINICAL PHARMACOLOGY, Studies With Other Vaccines in the full Prescribing Information). However, there are no data relating to simultaneous administration of VARIVAX with DTAP or OPV.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

VARIVAX has not been evaluated for its carcinogenic or mutagenic potential, or its potential to impair fertility.

Pregnancy

Category C

Animal reproduction studies have not been conducted with VARIVAX. It is not known whether VARIVAX can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Therefore, VARIVAX should not be administered to pregnant females. Further, pregnancy should be avoided for 3 months following vaccination (see CONTRAINDICATIONS).

Aurang Mohar

It is not known whether varicella vaccine virus is secreted in human milk. Therefore, because some viruses are secreted in human milk, caution should be exercised if VARIVAX is administered to a nursing woman.

Pediatric Use

No clinical data are available on safety or efficacy of VARIVAX in children less than one year of age, and administration to infants under 12 months of age is not recommended.

ADVERSE REACTIONS

In clinical trials, VARIVAX was administered to 11,102 healthy children, adolescents, and adults. VARIVAX was generally well-tolerated. In children, adolescents, and adults followed for up to 42 days, the adverse effects most frequently reported were as follows: fever (37°F [3.7°C] or in children and ≥38°F [100°F] in adults), injection site complaints (rash/swelling, redness, and/or pruritus), rash, pruritus, maternality, induction, stiffness); and varicella-like rash (reaction site and generalized).

In children, adolescents, and adults, adverse experiences reported at ≥1% frequency included, without limitation: headache, fever, diarrhea, abdominal pain, cough, irritability/nervousness, fatigue, distended belly, diarrhea, loss of appetite, vomiting, oliguria, diastolic hypertension, rash/contact rash, headache, itching, malaise, abdominal pain, other rash, nausea, eye complaints, chills, lymphadenopathy, myalgia, stiff neck, anorexia, leukopenia, squamous cell skin cancer, and constipation.

In children, pneumonitis (0.1%) and fibrotic lesions (0.1%) have been reported rarely; a causal relationship has not been established.

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

DOSAGE AND ADMINISTRATION

For SUBCUTANEOUS ADMINISTRATION

Do not inject intravenously.

Children 12 months to 12 years of age should receive a 0.5 mL dose administered subcutaneously. Adolescents and adults 13 years of age and older should receive a 0.5 mL dose administered subcutaneously at least 2 weeks apart.

VARIVAX MUST BE KEPT FROZEN AT A TEMPERATURE OF +5°F (−15°C) OR COLDER UNTIL IT IS RECONSTITUTED FOR INJECTION. STORAGE IN A FROST-FREE FREEZER WITH AN AVERAGE TEMPERATURE OF +5°F (−15°C) OR COLDER IS ACCEPTABLE. THE SOLUTION SHOULD BE STORED SEPARATELY AT ROOM TEMPERATURE.

When reconstituted, VARIVAX suspension should be visually inspected for cloudiness and particulate matter. If the vaccine is cloudy or contains particulate matter, it should not be used. VARIVAX suspension that has been frozen should be discarded if it is discolored, frozen, or has lost the average temperature of +5°F (−15°C) or colder.

Do not reconstitute vaccine.

Do not give immune globulins including Varicella Zoster Immune Globulin concurrently with VARIVAX (see also PRECAUTIONS).

VARIVAX 
VARICELLA VIRUS VACCINE LIVE
(0ka/Merck)

Merk

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1995 Annual Meeting
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there's always something exciting to do, see, or taste...from the cable cars to Fisherman's Wharf, from North Beach, Chinatown, or the new Yerba Buena Gardens adjacent to the Moscone Center...down to the Embarcadero, Telegraph Hill, or Ghirardelli Square. And don't stop there...there's lots more. This is everyone's favorite city.

Plan to attend the AAP Annual Meeting and bring your family. We look forward to seeing you there!