VARIVAX® III

Fact Sheet

VARIVAX® III

- VARIVAX® was the first varicella vaccine marketed in Canada. VARIVAX® III, like its predecessors (VARIVAX® and VARIVAX® II), contains the Oka/Merck strain of live, attenuated varicella virus.

Indication

- VARIVAX® III is indicated for vaccination against varicella in healthy individuals 12 months of age and older.

- The Canadian National Advisory Committee on Immunization (NACI), the Canadian Paediatric Society, the College of Family Physicians of Canada as well as the American Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Practitioners all recommend varicella vaccination.

Administration and Dosage

- VARIVAX® III is administered as a single subcutaneous dose of 0.5 ml to children 12 months to 12 years of age.

- Adults and adolescents 13 years of age and older should receive two doses of VARIVAX® III 0.5 ml, administered subcutaneously, four to eight weeks apart.

- VARIVAX® III can be administered with other childhood vaccines such as a measles, mumps and rubella vaccine (M-M-R® II).

Efficacy

- In clinical studies involving healthy children who received one dose of vaccine, varicella antibodies were present in 99.0 per cent at one year, 99.2 per cent at two years, 98.6 per cent at three years, 99.2 per cent at four years and 97.9 per cent at five years.
- Among healthy adolescents and adults, antibody levels against chickenpox were present in 97.9 per cent of the subjects, one year after the two recommended doses of vaccine.

Immunogenicity

- The gpELISA (not available commercially) is a test used to detect both the presence and the amount of varicella antibodies.

- A recent study[1] to establish the relationship between the presence and the amount of antibodies and the risk of developing varicella showed that a gpELISA ≥ 5 units, six weeks after vaccination, was a good predictor of long-term protection against varicella for at least seven years.

- The children who did not reach a gpELISA ≥ 5 units, six weeks after vaccination, were 3.5 times more likely to have reduced protection and develop mild chickenpox in the following years.

- A subsequent study[2] reviewed the gpELISA levels of VARIVAX® and VARILRIX™. Six weeks after vaccination, 95.2 per cent and 97.1 per cent of individuals receiving the Oka/Merck varicella vaccine VARIVAX® reached a gpELISA ≥ 5 units compared to 85.6 per cent for the Oka-RIT varicella vaccine (VARILRIX™).

Length of Protection

- Clinical trials involving healthy children, adolescents and adults susceptible to chickenpox have shown that the Oka/Merck varicella vaccine provides protection against the varicella-zoster virus for at least seven years. Long-term surveillance studies are underway to determine the presence of antibodies over a longer period of time.

Tolerability Profile and Adverse Reactions

- Clinical trials involving more than 17,000 healthy individuals have shown the Oka/Merck varicella vaccine to be generally well tolerated in individuals 12 months of age and older.

- In a double-blind placebo-controlled study among 956 healthy children and adolescents, the only adverse reactions that occurred at a significantly ($p<0.05$) greater rate in vaccinated recipients than in placebo recipients were pain and redness at the injection site and a varicella-like rash.

Contraindications

- VARIVAX® III is contraindicated for individuals hypersensitive to any component of the vaccine, including gelatin, and for those with a history of allergic reaction to neomycin. VARIVAX® III is generally contraindicated for individuals receiving immunosuppressive therapy or those with a history of congenital, hereditary or acquired immunodeficiency*.

- Pregnant women should not receive the vaccine and pregnancy should be avoided for three months after vaccination.

Long-term Experience

- To date, the Oka/Merck varicella vaccine relies on the most important body of clinical evidence with clinical trials involving more than 17,000 healthy individuals. Post-marketing studies involving more than 89,000 individuals have been done or are underway.

- More than 30 million doses of the vaccine have been administered in various countries including the United States, Brazil, Hong Kong, Malaysia, Taiwan and Canada.

References:

1 Li S et al., Inverse relationship between 6-week postvaccination varicella antibody response and likelihood of long-term breakthrough infection. Pediatr Infect Dis J 2002;21:337-342.

2 Lau YL, Vessey SJR, Chan ISF, et al. A comparison of safety, tolerability and immunogenecity of Oka/Merck varicella vaccine and VARILRIX™ in healthy children. Vaccine, 20, 2002; 2942-2949.

* For full details on the type of disease or therapy, please consult the product monograph.