

**Public Assessment Report
(Variation, Second Dose)**

PROQUAD

INFORMASI PRODUK

Nama obat jadi	:	ProQuad
Bentuk sediaan	:	Serbuk Injeksi
Zat berkhasiat	:	- Live attenuated measles virus (Enders' Edmonston strain) not less than 3,00 log₁₀ TCID₅₀ - Live attenuated mumps virus (Jeryl Lynn™ strain) not less than 4,30 log₁₀ TCID₅₀ - Live attenuated rubella virus (RA 27/3 strain) not less than 3,00 log₁₀ TCID₅₀ - Live attenuated varicella (Oka/Merck strain) not less than 3,99 log₁₀ PFU
Kemasan	:	Dus, 1 vial @ 0,5 ml (1 dose) + 1 vial pelarut
Pendaftar	:	PT. Merck Sharp Dohme Pharma Tbk, Indonesia
Produsen	:	Merck Sharp & Dohme Corp., West Point, USA dirilis oleh Merck Sharp & Dohme B.V., Haarlem, Netherlands
Status registrasi	:	Registrasi Variasi (Indikasi dan posologi baru)
Indikasi yang diajukan	:	<i>ProQuad is indicated for vaccination against measles, mumps, rubella, and varicella in individuals 12 months – <u>6 years</u> of age.</i>
Posologi yang diajukan	:	<i>Dosage</i> <i>Individuals 12 - 23 months of age should receive a single dose of ProQuad administered subcutaneous</i> <u>If a second dose of measles, mumps, rubella, and varicella vaccine is needed, ProQuad may be used. This dose is usually administered at 4 to 6 years of age after primary vaccination with M M R II and VARIVAX</u> <u>If the first dose of a measles-containing vaccine is given between 6 months of age and less than 12 months of age (in an at-risk situation such as measles outbreak, or due to official recommendations) the response to the vaccine may be adversely influenced by circulating maternal antibodies. Therefore, another dose of a measles-containing vaccine should be given at 12 months of age or later. A subsequent (third) dose can be administered if warranted by official recommendations for a measles-containing vaccine.</u>

Evaluasi Khasiat dan Keamanan

- Hasil studi P014 menunjukkan *baseline* titer antibodi untuk Measles, Mumps, Rubella, dan Varicella yang masih sangat tinggi, yaitu Measles (97,7%), Mumps (96,0%), Rubella (97,7%), dan Varicella (96,0%), tidak mendukung pengajuan pemberian *booster*.
- Laporan dari *active surveillance sites* ke CDC bahwa jumlah kasus varicella tetap terjadi secara konsisten atau sedikit menurun, dan wabah tetap berlangsung setelah pemberian 1-dosis vaksin varicella sehingga CDC merekomendasikan pemberian 2-dosis vaksin yang mengandung varicella. Berdasarkan pertimbangan ini, WHO dan IDAI merekomendasikan penggunaan 2-dosis vaksin yang mengandung measles.

KEPUTUSAN

Diterima untuk perubahan indikasi (12 bulan hingga 6 tahun) dan posologi (*booster* usia 4 hingga 6 tahun) sebagaimana yang diajukan.

Indikasi

ProQuad is indicated for vaccination against measles, mumps, rubella, and varicella in individuals 12 months – 6 years of age.

Posologi

Dosage

Individuals 12 - 23 months of age should receive a first dose of ProQuad administered subcutaneous.

If a second dose of measles, mumps, rubella, and varicella vaccine is needed, ProQuad may be used. This dose is usually administered at 4 to 6 years.

If the first dose of a measles-containing vaccine is given between 6 months of age and less than 12 months of age (in an at-risk situation such as measles outbreak, or due to official recommendations) the response to the vaccine may be adversely influenced by circulating maternal antibodies. Therefore, another dose of a measles-containing vaccine should be given at 12 months of age or later. A subsequent (third) dose can be administered if warranted by official recommendations for a measles-containing vaccine.