

Yukon Immunization Program Manual

Section 8: Biological Products

MMR & MMRV Vaccines

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Measles/Mumps/Rubella Vaccine (MMR)			PRIORIX®, MMRII®	
Manufacturer	PRIORIX®	GlaxoSmithKline	Biological Classification	Live, attenuated virus vaccine
	MMRII®	Merck		
INDICATIONS	SCHEDULE			
	Routine Schedule for Children (12 months to 18 years)		1st Dose: 0.5 mL SC at 12 months 2nd Dose: 0.5 mL SC at 4-6 yrs ⓘ MMR-V combined products may be used to complete series.	
	Health Care Workers (regardless of year of birth, See Table 1. Completing MMR Vaccine Series):		1st Dose: 0.5 mL SC 2nd Dose: 0.5 mL SC ⓘ	
	Adults born after 1970 (See Table 1. Completing MMR Vaccine Series):		1st Dose: 0.5 mL SC 2nd Dose: 0.5 mL SC ⓘ	
	Post-exposure prophylaxis		Follow Yukon CDC Pep Guidelines	
	ⓘ Minimum Spacing: There must be at least 4 weeks between MMR doses. ⓘ Outbreak management: Outbreak management guidance may override routine eligibility and spacing requirements. Follow YCDC, YIP, and CMOH direction.			

Table 1. Completing MMR Vaccine Series

Review immunization history to confirm adequate protection. Some older records may include mono/bivalent vaccines.

Age Group	Doses of Measles containing vaccine	Doses of Mumps containing vaccine	Doses of Rubella containing vaccine	Doses of MMR in the absence of historical record
NON-HEALTH CARE WORKER				
Clients 12 months to 18 years	2	2	1	2
Adults 19 years and older, born in 1970 or after	2	1 ¹ ... ¹ 2 doses if post-secondary student, military, or traveling to endemic country.	1	2
All clients born before 1970	Consider immune due to natural infection. Follow YCDC outbreak management guidance if applicable.		0	0
HEALTH CARE WORKER				
All Health Care Workers (any year of birth)	2	2	1	2

CONTRAINDICATIONS	• History of anaphylactic reaction to a previous dose of a measles/mumps/rubella-containing vaccine or to any component of the product. • Immunocompromised individuals: Live vaccines are generally contraindicated in individuals who are moderately to severely immunocompromised. Physician or specialist recommendation and Yukon Immunization Program approval are required. • Family history of congenital immunodeficiency. See Yukon Immunization Program Manual, Section 4 for details. • Pregnancy: Avoid pregnancy for 1 month following immunization. • Significant thrombocytopenia: Physician-diagnosed significant thrombocytopenia after a previous MMR dose with no other cause identified. Consult Yukon Immunization Program for direction. • Active untreated tuberculosis (TB). • Individuals with acute febrile illness.
PRECAUTIONS AND SPECIAL CONSIDERATIONS	• Immunocompromised individuals: The decision to immunize an immunocompromised individual with a live vaccine must follow consultation with the physician or medical specialist and be approved by the Yukon Immunization Program. Any approved live vaccine must be separated from other live vaccines by at least 4 weeks. • Recent immune globulin or blood products: Recent administration of an immune globulin preparation, including RhIG or a blood product, may interfere with vaccine response (see CIG, 2013, Recent Administration of Human Immune Globulin Products). • Clients 6 to 11 months of age attending large gatherings with known unvaccinated populations may be considered for early MMR dose. Please consult YIP. • Clients who have previously received an early MMR dose (<12 months of age) must still receive 2 valid doses after 12 months of age, at appropriate intervals. • Spacing of live vaccines: Live vaccines must be given on the same day or separated by at least 4 weeks. • Egg allergy: Egg allergy, including anaphylaxis, is not a contraindication for MMR immunization. • TB skin testing: TB skin testing should be performed on the same day as MMR immunization or delayed for at least 4 weeks after immunization.

PREGNANCY AND LACTATION	• Pregnancy: No controlled reproduction studies have been conducted. There is no evidence of teratogenicity when inadvertently administered during pregnancy. • Breastfeeding: Recent studies indicate lactating postpartum women immunized with live attenuated vaccine may secrete the virus in breast milk. • The vaccine **may be given to individuals who are lactating and feeding their milk to infants or children.
INTERCHANGEABILITY	MMR vaccine products may be used interchangeably if the recommended dose and schedule are followed.
RECONSTITUTION AND DILUTION	1. Check the appearance of the contents in each vial and diluent. 2. Use only the diluent supplied by the manufacturer. 3. Disinfect the neck of the ampoule or rubber stopper of the vial and allow it to dry. 4. Using sterile syringe and needle, add the entire contents of the diluent to the vaccine vial. 5. Gently shake the reconstituted vaccine until the powder is completely dissolved. 6. Withdraw the entire reconstituted vaccine into a syringe and administer the total volume.
ADMINISTRATION	MMR vaccine should be given subcutaneously.
CONCURRENT ADMINISTRATION	• MMR vaccine products may be given at the same time as other live vaccines OR separated by an interval of at least 4 weeks. • MMR may also be administered simultaneously with inactivated vaccines.
SEROLOGICAL TESTING	Serology is not routinely recommended before or after immunization. Assessment of vaccination history is preferred. See Table 1 for MMR series. If serology is available, immunity is defined as follows: Mumps: • History of lab-confirmed mumps disease • Note: Positive mumps IgG is not reliable evidence of immunity

SEROLOGICAL TESTING	Measles: • 2 documented doses of measles-containing vaccine, OR • Serology showing measles IgG positive, OR • History of lab-confirmed measles disease • Note: If 2 doses are documented, a 3rd dose is not required even if serology is negative or indeterminate Rubella: • Vaccine history, OR • Serology showing rubella IgG positive, OR • History of lab-confirmed rubella disease • Note: Routine serology is not recommended except in prenatal care. Offer 2nd dose to women of childbearing age and healthcare workers with negative rubella serology.	
VACCINE COMPONENTS	Priorix®	M-M-R® II
	Each 0.5 mL dose of reconstituted vaccine contains:	
	• Not less than 10^{3.0} CCID₅₀ of the Schwarz measles* strain • Not less than 10^{3.7} CCID₅₀ of the RIT 4385 mumps* strain (derived from the Jeryl Lynn strain) • Not less than 10^{3.0} CCID₅₀ of the Wistar RA 27/3 rubella** virus strain • Amino acids • Lactose • Mannitol • Sorbitol • Sterile Water (diluent) • Residual neomycin sulphate	• Measles virus*, Enders' Edmonston strain (live, attenuated) >1,000 CCID₅₀ • Mumps virus*, Jeryl Lynn® (B level) strain (live, attenuated) >5,000 CCID₅₀ • Rubella virus**, Wistar RA 27/3 strain (live, attenuated) >1,000 CCID₅₀ • Sorbitol • Hydrolyzed gelatin • Medium 199 with Hank's salts • Sodium phosphate monobasic & dibasic • Sucrose • Sodium bicarbonate • Minimum Essential Medium, Eagle • Potassium phosphate dibasic • Neomycin • Monosodium L-glutamate Monohydrate • Potassium phosphate monobasic • Phenol red • Recombinant human albumin • Residual fetal bovine serum • Sterile water (diluent)
	Notes: Measles and mumps viruses produced in chick embryo cells ** Rubella virus produced in MRC-5 human diploid cells (Priorix®) / human diploid lung fibroblasts (M-M-R® II)	

BOVINE/PORCINE PRODUCTS	Priorix®	M-M-R® II
	Bovine Products:	
	- Contains lactose and galactose derived from bovine milk. - Fetal bovine serum is used as raw materials during the routine manufacturing process.	Manufacturing process residual: fetal bovine serum.
	Porcine Products:	
	Trypsin (isolated from porcine pancreas) is used as raw materials during routine manufacturing process.	Gelatin used in manufacturing originates from porcine skin collagen
BLOOD/BLOOD PRODUCTS	Priorix®	M-M-R® II
	The rubella virus is propagated in human diploid cell culture (MRC-5 lung fibroblasts).	- The rubella virus is propagated in human diploid cell culture (MRC-5 lung fibroblasts). - The manufacturing process includes residual recombinant human albumin.
APPEARANCE	Priorix®	M-M-R® II
	Prior to reconstitution:	
	Whitish to slightly pink cake or powder	Light yellow compact crystalline plug
	Reconstituted vaccine:	
	May vary in colour from clear peach to fuchsia pink due to minor pH variation; this does not affect potency.	Clear yellow.
	Note: If other variation is observed, do not use the vaccine.	
LATEX	M-M-R® II & Priorix® do not contain latex.	

EXPECTED REACTIONS	• Local: Pain, swelling, redness at injection site; possible axillary or groin lymph node swelling or tenderness. • Systemic: Fever, rash (typically appears 5–12 days after immunization), malaise, headache, nausea, and myalgia. • Rare: See the product monograph for a full list of rare adverse events, including thrombocytopenia, encephalitis, acute transient arthritis/arthralgia, and Guillain-Barré Syndrome (GBS).
STORAGE AND HANDLING	• Temperature: Store M-M-R® II and Priorix® in a refrigerator at 2–8 °C. • Do NOT freeze. • Store in the original packaging to protect from light. • After reconstitution: Administer the vaccine as soon as possible. If not used immediately, keep refrigerated and use within 8 hours.
REFERENCES AND RESOURCES	
NACI Statement Priorix® Monograph MMR_II Monograph	

Measles/Mumps/Rubella/Varicella Vaccine (MMRV)			Priorix-Tetra®, ProQuad®	
Manufacturer	Priorix-Tetra®	GlaxoSmithKline	Biological Classification	Live, attenuated virus vaccine
	ProQuad®	Merck		
INDICATIONS	SCHEDULE			
	Routine Schedule for Children (4-6 years of age)		1 Dose: 0.5-0.7 mL SC at 4-6 yrs of age. MMR-V combined product used to complete the second dose of MMR and Varicella series.	
	Children 4–12 years (inclusive) with no previous dose of MMR or Varicella		Dose 1: 0.5-0.7 mL SC, Dose 2: 0.5-0.7 mL SC, spaced ≥12 weeks apart	
	Children 7–12 years (inclusive) with only 1 previous dose of MMR and <u>and</u> Varicella		1 Dose: 0.5-0.7 mL SC MMR-V combined product used to complete the second dose of MMR and Varicella series.	
	Minimum spacing of MMRV is 4 weeks from previous MMR and 12 weeks from previous Varicella products.			
CONTRAINDICATIONS	• History of anaphylactic reaction to a previous dose of a measles/mumps/rubella/varicella-containing vaccine or to any component of the product. • Immunocompromised individuals: Live vaccines are generally contraindicated in individuals who are moderately to severely immunocompromised. Physician or specialist recommendation and Yukon Immunization Program approval are required. • Family history of congenital immunodeficiency. See Yukon Immunization Program Manual, Section 4 for details. • Pregnancy: Avoid pregnancy for 1 month following immunization. • Significant thrombocytopenia: Physician-diagnosed significant thrombocytopenia after a previous MMR dose with no other cause identified. Consult Yukon Immunization Program for direction. • Active untreated tuberculosis (TB). • Individuals with acute febrile illness.			

Measles/Mumps/Rubella/Varicella Vaccine (MMRV) Priorix-Tetra®, ProQuad®	
PRECAUTIONS AND SPECIAL CONSIDERATIONS	• Immunocompromised individuals: The decision to immunize an immunocompromised individual with a live vaccine must follow consultation with the physician or medical specialist and be approved by the Yukon Immunization Program. Any approved live vaccine must be separated from other live vaccines by at least 4 weeks. • Recent immune globulin or blood products: Recent administration of an immune globulin preparation, including RhIG or a blood product, may interfere with vaccine response (see CIG, 2013, Recent Administration of Human Immune Globulin Products). • Spacing of live vaccines: Live vaccines must be given on the same day or separated by at least 4 weeks. • Egg allergy: Egg allergy, including anaphylaxis, is not a contraindication for MMR immunization. • TB skin testing: TB skin testing should be performed on the same day as MMR immunization, or delayed for at least 4 weeks after immunization. • Salicylates: Individuals under 18 years of age should avoid taking salicylates for 6 weeks following MMR-V immunization. Consult the Yukon Immunization Program if the child is on chronic salicylate therapy. • Antiviral medication: Consult the Yukon Immunization Program for children on long-term antiviral medication. • Age restrictions: MMRV is licensed in Canada for children 12 months to 12 years of age. The Yukon Immunization Program does not recommend this product for children under 4 years of age due to an increased risk of febrile seizures.
PREGNANCY AND LACTATION	Product not indicated for this population.
INTERCHANGEABILITY	MMR-V vaccine products may be used interchangeably.
RECONSTITUTION AND DILUTION	1. Check the appearance of the contents in each vial and diluent. 2. Use only the diluent supplied by the manufacturer. 3. Disinfect the neck of the ampoule or rubber stopper of the vial and allow it to dry. (Note: Disinfection is not required if the diluent is supplied in a pre-filled syringe.) 4. Using a sterile syringe and needle, add the entire contents of the diluent to the vaccine vial. 5. Gently shake the reconstituted vaccine until the powder is completely dissolved. 6. Withdraw the entire reconstituted vaccine into a syringe and administer the total volume. (The final volume may be between 0.5 mL and 0.7 mL for this product.) 7. A new needle should be used to administer the vaccine.

Measles/Mumps/Rubella/Varicella Vaccine (MMRV)		Priorix-Tetra®, ProQuad®
ADMINISTRATION	MMR-V vaccine should be given subcutaneously.	
CONCURRENT ADMINISTRATION	- MMRV vaccine products may be given at the same time as other inactivated vaccines. - MMRV may also be administered simultaneously with other live vaccines or separated by at least 4 weeks if not given on the same day.	
SEROLOGICAL TESTING	Serological testing is not routinely recommended before or after immunization.	
VACCINE COMPONENTS	Priorix-Tetra®	ProQuad®
	Each 0.5 mL dose of reconstituted vaccine contains:	
	- Not less than 10^3 CCID₅₀ of Schwarz measles* strain - Not less than $10^{4.4}$ CCID₅₀ of RIT 4385 mumps* strain (derived from Jeryl Lynn strain) - Not less than 10^3 CCID₅₀ of Wistar RA 27/3 rubella** virus strain - Not less than $10^{3.3}$ PFU OKA varicella** virus strain - Amino acids for injection - Lactose - Mannitol - Sorbitol - Residual neomycin sulphate - Sterile water (diluent)	- Not less than 3.00 log₁₀ TCID₅₀ measles* virus (Ender's attenuated Edmonston strain) - Not less than 4.30 log₁₀ TCID₅₀ mumps* virus (Jeryl Lynn [B level] strain) - Not less than 3.00 log₁₀ TCID₅₀ rubella** virus (Wistar RA 27/3 propagated in WI-38 human diploid lung fibroblasts) - Not less than 3.99 log₁₀ PFU varicella** virus (Oka/Merck strain propagated in MRC-5 cells) - Sucrose - Hydrolyzed gelatin - Urea - Sodium chloride - Sorbitol - Monosodium L-glutamate - Sodium phosphate - Recombinant human albumin - Sodium bicarbonate - Potassium phosphate - Potassium chloride - Neomycin - Sterile water (diluent).

Measles/Mumps/Rubella/Varicella Vaccine (MMRV) Priorix-Tetra®, ProQuad®		
	Notes: Measles and mumps viruses produced in chick embryo cells ** Rubella virus produced in MRC-5 human diploid cells (Priorix-Tetra®) and WI-38 or MRC-5 human diploid lung fibroblasts (ProQuad®) *ProQuad® varicella virus propagated in MRC-5 cells	
BOVINE/PORCINE PRODUCTS	Priorix-Tetra®	ProQuad®
	Bovine Products:	
	- Contains lactose and galactose derived from bovine milk. - Fetal bovine serum is used as raw material during the routine manufacturing process.	Manufacturing process residual: fetal bovine serum.
	Porcine Products:	
	Trypsin (isolated from porcine pancreas) is used as raw material during manufacturing.	Gelatin used in manufacturing originates from porcine skin collagen.
BLOOD/BLOOD PRODUCTS	Priorix-Tetra®	ProQuad®
	The rubella virus is propagated in human diploid cell culture (MRC-5 lung fibroblasts).	- The rubella virus is propagated in human diploid cell culture (MRC-fibroblasts). - Manufacturing process residual: human albumin.
APPEARANCE	Priorix-Tetra®	ProQuad®
	Prior to reconstitution:	
	Whitish to slightly pink cake or powder	White to pale light yellow compact crystalline plug
	Reconstituted vaccine:	

Measles/Mumps/Rubella/Varicella Vaccine (MMRV)			Priorix-Tetra®, ProQuad®
	May vary in colour from clear peach to fuchsia pink due to minor pH variation; this does not affect potency.	Pale yellow to light pink.	
	Note: If any other variation is observed, do not use the vaccine.		
LATEX	ProQuad® & Priorix-Tetra® do not contain latex.		
EXPECTED REACTIONS	• Local: Pain, swelling, redness at injection site; possible axillary or groin lymph node swelling or tenderness. • Systemic: Fever, rash (typically appears 5–12 days after immunization), malaise, headache, nausea, and myalgia. • Rare: See the product monograph for a full list of rare adverse events, including thrombocytopenia, encephalitis, acute transient arthritis/arthralgia, and Guillain-Barré Syndrome (GBS).		
STORAGE AND HANDLING	• Temperature: Store ProQuad® and Priorix-Tetra® in a refrigerator at 2–8 °C. • Do NOT freeze. • Store in the original packaging to protect from light. • After reconstitution: Administer the vaccine as soon as possible. ○ ProQuad® must be discarded if not used within 30 minutes. ○ Priorix-Tetra® must be discarded if not used within 8 hours (keep refrigerated).		
REFERENCES AND RESOURCES			
NACI Statement Priorix-Tetra® Monograph ProQuad® Monograph			